

Exhibit B

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4

5 IN RE: ETHICON, INC.,) Master File No.
PELVIC REPAIR SYSTEMS) 2:12-MD-02327
6 PRODUCTS LIABILITY) MDL 2327
LITIGATION,) JOSEPH R. GOODWIN
7) U.S. DISTRICT JUDGE

-----) -----

8 THIS DOCUMENT RELATES TO) Case No.
) 2:12-CV-05201

9 JO HUSKEY, ET AL., V.)
ETHICON, INC.,)
10)
-----) -----

11 TONYA AND GARY EDWARDS,) Case No.
12 V.) 2:12-cv-09972
13 ETHICON, INC., ET AL.,)
14 -----) -----

15

16

17 The videotaped deposition of WENXIN ZHENG, M.D.,
18 called by the Plaintiffs for examination, taken pursuant
19 to the Federal Rules of Civil Procedure of the United
20 States District Courts pertaining to the taking of
21 depositions, taken before BONNIE J. HUMM, RPR, Certified
22 Reporter in the State of Arizona, No. 50722, at the
23 Westin La Paloma, 3800 East Sunrise Drive, Tucson,
24 Arizona, on April 3, 2014, commencing at 10:11 a.m.

25

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<p>1 APPEARANCES:</p> <p>2 For the Plaintiffs:</p> <p>3 MOTLEY RICE LLC</p> <p>4 By: Margaret M. Thompson, M.D., J.D.</p> <p>5 28 Bridgeside Boulevard</p> <p>6 Mt. Pleasant, South Carolina 29464</p> <p>7 (843) 518-0645</p> <p>8 mthompsonmd@gmail.com</p> <p>9</p> <p>10 For the Huskey Plaintiffs:</p> <p>11 MOTLEY RICE LLC</p> <p>12 By: Fidelma L. Fitzpatrick, Esq.</p> <p>13 321 South Main Street</p> <p>14 Providence, Rhode Island 02903</p> <p>15 (401) 457-7728</p> <p>16 ffitzpatrick@motleyrice.com</p> <p>17</p> <p>18 For the Edwards Plaintiffs:</p> <p>19 MUELLER LAW LLC</p> <p>20 By: John Fabry, Esq.</p> <p>21 404 West 7th Street</p> <p>22 Austin, Texas 78701</p> <p>23 (512) 478-1236</p> <p>24 john.fabry@muellerlaw.com</p> <p>25</p>	<p>1 I N D E X</p> <p>2 WITNESS PAGE</p> <p>3 WENXIN ZHENG, M.D.</p> <p>4 Examination by Ms. Thompson 10</p> <p>5 Examination by Mr. Snell 270</p> <p>6 Re-Examination by Ms. Thompson 287</p> <p>7</p> <p>8</p> <p>9 E X H I B I T S</p> <p>10 NUMBER DESCRIPTION PAGE</p> <p>11 1 Notice of Deposition Pursuant to Rule 32</p> <p>12 30 and Document Requests Pursuant to</p> <p>13 Rule 34 of Wenxin Zheng, M.D.</p> <p>14 2 PowerPoints brought by Dr. Zheng with 36</p> <p>15 accompanying color photographs of</p> <p>16 slides: Comparisons of HE pictures to</p> <p>17 those after polarization; Vascular</p> <p>18 pictures from Edwards; Neurofilament</p> <p>19 staining; Sections are fragmented in</p> <p>20 recent recuts from Blocks A and B</p> <p>21 3 Article: Pathologic Evaluation of 47</p> <p>22 Explanted Vaginal Mesh:</p> <p>23 Interdisciplinary Experience From a</p> <p>24 Referral Center, Tovia M. Smith, M.D.,</p> <p>25 et al.</p>
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<p>1 APPEARANCES CONTINUED:</p> <p>2 For the Defendants Ethicon, Inc. and</p> <p>3 Johnson & Johnson:</p> <p>4 BUTLER SNOW LLP</p> <p>5 By: Nils B. (Burt) Snell, Esq.</p> <p>6 500 Office Center Drive, Suite 400</p> <p>7 Fort Washington, Pennsylvania 19034</p> <p>8 (267) 513-1885</p> <p>9 burt.snell@butlersnow.com</p> <p>10</p> <p>11 For the Defendants Ethicon, Inc. and</p> <p>12 Johnson & Johnson:</p> <p>13 BUTLER SNOW LLP</p> <p>14 By: M. Andrew Snowden, Esq.</p> <p>15 150 3rd Avenue South, Suite 1600</p> <p>16 Nashville, Tennessee 37201</p> <p>17 (615) 651-6700</p> <p>18 andy.snowden@butlersnow.com</p> <p>19</p> <p>20 Also Present: Laurie Wilmer, Videographer</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 E X H I B I T S</p> <p>2 NUMBER DESCRIPTION PAGE</p> <p>3 4 3-21-14 Expert Report of Dr. Zheng 66</p> <p>4 5 Article: On the mechanisms of 67</p> <p>5 biocompatibility, David F. Williams</p> <p>6 6 Article: The Argument for Lightweight 86</p> <p>7 Polypropylene Mesh in Hernia Repair,</p> <p>8 William S. Cobb, et al.</p> <p>9 7 Article: Minimally Invasive Synthetic 109</p> <p>10 Suburethral Sling Operations for</p> <p>11 Stress Urinary Incontinence in Women:</p> <p>12 A Short Version Cochrane Review, J.</p> <p>13 Ogah, et al.</p> <p>14 8 Two color photographs of blocks 123</p> <p>15 received by Dr. Zheng</p> <p>16 9 Gross picture of explanted mesh from 124</p> <p>17 Tonya Edwards</p> <p>18 10 Figure 4 on page 13 of Dr. Zheng's 134</p> <p>19 report</p> <p>20 11 Operative report for Tonya Edwards 138</p> <p>21 12 Figure 5 on page 14 of Dr. Zheng's 143</p> <p>22 report</p> <p>23 13 Figure 8 on page 17 of Dr. Zheng's 148</p> <p>24 report</p> <p>25</p>

Wenxin Zheng, M.D.

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3	14	Document in French from Jean de Leval, 163	3	33	Photograph from Dr. Zheng showing bark 254
4		M.D.	4		like layer
5	15	Article: Randomized Trial of 166	5	34	(Number skipped)
6		Tension-Free Vaginal Tape and	6	35	Figure 25 (left-hand side only) from 257
7		Tension-Free Vaginal Tape-Obturator	7		page 45 of Dr. Iakovlev's report
8		for Urodynamic Stress Incontinence in	8	36	Figures 22 and 23 from page 40 of Dr. 260
9		Women, Roderick Teo, et al.	9		Iakovlev's report
10	16	Figure 5 (top half only) from page 21 196	10	37	Invoice tally for Dr. Wenxin Zheng's 288
11		of Dr. Iakovlev's report	11		expert work on Carolyn Lewis v.
12	17	Figure 6 on page 15 of Dr. Zheng's 201	12		Ethicon, et al.
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14	18	Article: Materials Characterization of 206	14		
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22		Polyvinylidene Fluoride and	22		
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24		Surgery, Celine Mary, et al.	24		
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1	NUMBER	EXHIBITS DESCRIPTION PAGE	1	THE VIDEOGRAPHER: I'm Laurie Wilmer with	
2	21	Group exhibit of 18 pages of 214	2	Green Legal Video, Tucson, Arizona. The court reporter	
3		documents, nonsequentially numbered	3	is Bonnie Humm with Kathy Fink & Associates, 2819 East	
4	22	Figure TE1 (top half only) from page 225	4	22nd Street, Tucson, Arizona.	
5		58 of Dr. Iakovlev's report	5	This is the videotaped deposition of	
6	23	Figure TE2 (left-hand side only) from 226	6	Wenxin Zheng in the matter of Jo Huskey and Allen Huskey	
7		page 59 of Dr. Iakovlev's report	7	versus Ethicon, Inc., et al., Southern District of West	
8	24	Figure TE5 from page 63 of Dr. 229	8	Virginia, Charleston Division, case number 2:12-cv-05201.	
9		Iakovlev's report	9	The deposition is being held in the Westin	
10	25	Figure TE7a (left-hand side only) from 230	10	La Paloma, 3800 East Sunrise Drive, Tucson, Arizona, on	
11		page 65 of Dr. Iakovlev's report	11	April 3rd, 2014. The time is 10:11 a.m.	
12	26	Figure TE8 (left-hand side only) from 232	12	Will everyone present please introduce	
13		page 67 of Dr. Iakovlev's report	13	themselves.	
14	27	Figure TE9a (left-hand side only) from 236	14	MS. THOMPSON: Margaret Thompson on behalf	
15		page 68 of Dr. Iakovlev's report	15	of the plaintiffs.	
16	28	Photograph by Dr. Zheng showing bark 245	16	MS. FITZPATRICK: Fidelma Fitzpatrick on	
17		like areas	17	behalf of Jo Huskey.	
18	29	Figure 24c from page 43 of Dr. 246	18	MR. FABRY: John Fabry. This case also or	
19		Iakovlev's report	19	this deposition also involves Tonya Edwards as a	
20	30	Figure 24d from page 44 of Dr. 249	20	plaintiff, and I represent her in this matter.	
21		Iakovlev's report	21	MR. SNELL: Burt Snell representing	
22	31	Photograph by Dr. Zheng using 252	22	Ethicon and Johnson & Johnson.	
23		polarization	23	MR. SNOWDEN: Andy Snowden on behalf of	
24	32	Photograph by Dr. Zheng showing bark 254	24	Ethicon and Johnson & Johnson.	
25		like layer	25	THE VIDEOGRAPHER: The court reporter will	

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1 please swear in the witness.
 2 WENXIN ZHENG, M.D.,
 3 having been first duly sworn by the Certified Reporter to
 4 tell the truth, the whole truth, and nothing but the
 5 truth, testified as follows:
 6 MS. THOMPSON: Good morning, Dr. Zheng.
 7 THE WITNESS: Good morning.
 8 EXAMINATION
 9 BY MS. THOMPSON:
 10 Q. Would you please state your name.
 11 A. Wenxin Zheng.
 12 Q. And what is your current position?
 13 A. I'm a professor of pathology as well as a
 14 professor of obstetrics and gynecology in the University
 15 of Arizona.
 16 Q. And have you ever had your deposition taken
 17 before?
 18 A. Yes, I did.
 19 Q. About how many times?
 20 A. Three to four times.
 21 Q. And how many of those involved mesh or
 22 anything related to mesh?
 23 A. Previously there was one.
 24 Q. And what was that regarding?
 25 A. Regarding a TVT mesh.

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1 Q. Was that in the Lewis matter?
 2 A. That's Lewis, yes.
 3 Q. And I believe that was in December of last
 4 year --
 5 A. Correct.
 6 Q. -- correct?
 7 What were the other two or three
 8 depositions regarding?
 9 A. That's mainly in the gynecological cancers.
 10 Q. Medical malpractice cases?
 11 A. Medical malpractice cases, yes.
 12 Q. Did they revolve around not diagnosing a
 13 cancer?
 14 A. Either missing -- missed a diagnosis or wrong
 15 interpretations.
 16 Q. And in those, did you testify for the
 17 plaintiff or the defendant, the doctor?
 18 A. One I think is for plaintiff; the other is for
 19 defendant.
 20 Q. Have you been designated as an expert in any
 21 mesh cases other than Ms. Lewis and the cases that we
 22 have here today, Ms. Huskey and Ms. Edwards?
 23 A. I don't think I'm an expert for overall, like
 24 the mesh and related issues, but I have been considered
 25 as an expert in the GYN pathology, gynecological

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1 pathology.
 2 MR. SNELL: I don't think he understood
 3 your question.
 4 MS. THOMPSON: Yes.
 5 (By Ms. Thompson)
 6 Q. Have any --
 7 MR. SNELL: I can tell you he hasn't been
 8 designated in any other cases.
 9 She's asking have you been designated in
 10 other cases like the Huskey, Lewis, Edwards --
 11 THE WITNESS: Oh, no. I'm sorry. No.
 12 MR. SNELL: -- meaning you have done a
 13 report?
 14 THE WITNESS: No.
 15 (By Ms. Thompson)
 16 Q. So are there any other companies that have
 17 consulted you about being an expert?
 18 A. No.
 19 Q. So Ethicon is the only company that you're
 20 working with currently regarding mesh?
 21 A. Correct.
 22 Q. Okay. And you understand today that we're
 23 here on behalf of Jo Huskey and Tonya Edwards, who are
 24 plaintiffs in the federal MDL litigation with a trial
 25 taking place in West Virginia, correct?

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1 A. Yes, I understand that.
 2 Q. And you have offered opinions on Tonya Edwards
 3 that are contained in your report, correct?
 4 A. Correct.
 5 Q. And in Jo Huskey's case, you are not able to
 6 provide specific comments about her pathology, correct?
 7 A. Correct.
 8 Q. Because she did not have a specimen that you
 9 were able to examine, correct?
 10 A. Yes.
 11 Q. So I then can assume that you do not intend to
 12 offer any opinions regarding her medical condition based
 13 on her pathology; is that correct?
 14 MR. SNELL: Form.
 15 Go ahead.
 16 A. Based on pathology, I'm not able to provide
 17 any opinion, because there's no material for me to
 18 review.
 19 But I do have some opinion regarding the
 20 plaintiffs' expert, because Dr. Iakovlev already
 21 mentioned or made some statements regarding Huskey's
 22 case.
 23 (By Ms. Thompson)
 24 Q. So your only opinions, then, will be
 25 responsive to Dr. Iakovlev's opinions; is that correct?

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<p>1 A. Correct.</p> <p>2 Q. So as we go through the day, if I ask you a</p> <p>3 question that you don't understand, like I just did a</p> <p>4 minute ago --</p> <p>5 A. Sure.</p> <p>6 Q. -- which wasn't a very good question, let's</p> <p>7 make sure you understand it before we go on. I'll be</p> <p>8 happy to --</p> <p>9 A. Sure.</p> <p>10 Q. -- to rephrase. I'm not a pathologist. I</p> <p>11 hope I do better than third grade, which I think is what</p> <p>12 Mr. Monsour said he got to. I'm going to attempt to get</p> <p>13 at least to middle school. We'll see.</p> <p>14 A. Okay.</p> <p>15 Q. So you, in addition to your pathology</p> <p>16 expertise, you also trained in OB-GYN in China; is that</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Tell me a little bit about that training --</p> <p>20 A. Okay.</p> <p>21 Q. -- and how -- what the equivalent would be to</p> <p>22 the U.S. as far as residency or postgraduate.</p> <p>23 A. Okay. So basically after my graduation from</p> <p>24 medical school in China, then I went to a hospital -- the</p> <p>25 hospital name is called Hospital of Obstetrics and</p>	<p>1 A. I don't remember exactly how many other kinds,</p> <p>2 but this was the one name I think I kept in mind. That</p> <p>3 was a long time ago, yeah.</p> <p>4 Q. And I assume that you evaluated the patients</p> <p>5 preoperatively for their procedures?</p> <p>6 A. Usually, yeah, we have to do that.</p> <p>7 Q. And you took care of them postoperatively?</p> <p>8 A. Correct.</p> <p>9 Q. While they were in the hospital, I presume,</p> <p>10 correct?</p> <p>11 A. Uh-huh.</p> <p>12 Q. And did you see them back in the clinic</p> <p>13 afterwards?</p> <p>14 A. Some of those patients, just by chance they</p> <p>15 are doing clinical follow-up. Then if I were there, then</p> <p>16 I will see.</p> <p>17 Q. Did you also assist or participate in</p> <p>18 surgeries for prolapse?</p> <p>19 A. Oh, yes. That's a more common one than</p> <p>20 urinary incontinence in China at that time.</p> <p>21 Q. And what procedures did you perform or</p> <p>22 participate in for pelvic prolapse?</p> <p>23 A. Well, usually that's either transvaginal</p> <p>24 hysterectomy and/or transabdominal hysterectomy. I don't</p> <p>25 think at that time people were performing some kind of</p>
Page 15	Page 17
<p>1 Gynecology -- where I did my four years' residency</p> <p>2 training there. Within the four years, I have different</p> <p>3 rotations in different sections of obstetrics and</p> <p>4 gynecology. So that's basically equivalent to the four</p> <p>5 years' residency training in U.S.</p> <p>6 Q. And was that time equally divided between</p> <p>7 obstetrics and gynecology, similar to in the U.S.?</p> <p>8 A. Correct.</p> <p>9 Q. And I can assume, can't I, that the GYN</p> <p>10 portion included surgical training as well?</p> <p>11 A. Yes.</p> <p>12 Q. While you were doing your four years'</p> <p>13 residency in China, did you do surgery for stress urinary</p> <p>14 incontinence?</p> <p>15 A. I think because the residents they are not</p> <p>16 allowed to do independent surgery, but I did observe</p> <p>17 similar surgeries such as Burch-like surgeries.</p> <p>18 Q. And you assisted on surgeries?</p> <p>19 A. Right, uh-huh.</p> <p>20 Q. And you mentioned Burch. Was that one of the</p> <p>21 operations that you assisted on when you were doing your</p> <p>22 OB-GYN training in China?</p> <p>23 A. At that time, correct.</p> <p>24 Q. Were there any other procedures for stress</p> <p>25 incontinence that you assisted or participated in?</p>	<p>1 repair for those urinary -- for those prolapse patients.</p> <p>2 And doctors in China at the beginning usually will</p> <p>3 recommend to do more conservative surgery, conservative</p> <p>4 approach, rather than, you know, surgery to remove the</p> <p>5 organs.</p> <p>6 Q. What were the conservative approaches that</p> <p>7 were --</p> <p>8 A. Like Kegel exercise.</p> <p>9 Q. Did you participate or assist at anterior</p> <p>10 colporrhaphy?</p> <p>11 A. I heard that name, but I don't remember</p> <p>12 exactly if I did that kind of procedure.</p> <p>13 Q. It probably had a different name in Chinese?</p> <p>14 A. Yeah.</p> <p>15 Q. Perhaps?</p> <p>16 A. Right.</p> <p>17 Q. How about posterior colporrhaphy?</p> <p>18 A. That's why I said it's not very clear for me</p> <p>19 at that time whether those are correlated to such</p> <p>20 approach.</p> <p>21 Q. How about any kind of suspension of the uterus</p> <p>22 or the top of the vagina through an abdominal approach?</p> <p>23 A. I don't remember exactly, yeah.</p> <p>24 Q. Currently, you do not practice OB-GYN in terms</p> <p>25 of direct patient care; is that correct?</p>

<p style="text-align: right;">Page 18</p> <p>1 A. Correct.</p> <p>2 Q. So what are your responsibilities as a</p> <p>3 professor in the OB-GYN department?</p> <p>4 A. Mainly teaching. And also we -- I'm the</p> <p>5 person running the gynecological tumor board conference</p> <p>6 every week.</p> <p>7 Q. And you consider yourself a GYN pathologist;</p> <p>8 is that correct?</p> <p>9 A. Correct.</p> <p>10 Q. And your main interest in GYN pathology is</p> <p>11 tumors and particularly cancerous tumors; is that</p> <p>12 correct?</p> <p>13 MR. SNELL: Form.</p> <p>14 A. I think the main interest as a GYN pathologist</p> <p>15 covers all the specimens, no matter it's cancer or</p> <p>16 benign, you know, within the gynecological or woman's</p> <p>17 female genital tract. All these specimens come to my</p> <p>18 attention or come to my program.</p> <p>19 (By Ms. Thompson)</p> <p>20 Q. At least as far as publications go and</p> <p>21 lectures, presentations, wouldn't you agree with me that</p> <p>22 most of those revolve around tumors, GYN cancers?</p> <p>23 A. Correct.</p> <p>24 Q. Why did you choose pathology as a medical</p> <p>25 specialty?</p>	<p style="text-align: right;">Page 20</p> <p>1 pathology or GI pathology, they all belong to umbrella</p> <p>2 pathology called surgical pathology. So we have to have</p> <p>3 surgical pathology training first. Then can go to</p> <p>4 different subspecialties. So I'm -- overall I'm a</p> <p>5 surgical pathologist.</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. And surgical pathology is part of clinical</p> <p>8 pathology --</p> <p>9 A. Yes.</p> <p>10 Q. -- correct?</p> <p>11 A. We're dealing with all the specimen from the</p> <p>12 surgeries.</p> <p>13 Q. Do you consider yourself a clinician?</p> <p>14 A. Yes. Pathologist is a clinician.</p> <p>15 Q. And as a pathology -- as a pathologist, isn't</p> <p>16 observation one of the most important things that you do?</p> <p>17 A. It's not observation. I think in the clinical</p> <p>18 side, we provide diagnosis for patient care. That's the</p> <p>19 main thing.</p> <p>20 Q. So you provide diagnoses for patient care</p> <p>21 based on examination of the pathology?</p> <p>22 A. Based on examination of the specimen we</p> <p>23 receive and also, you know, relevant clinical</p> <p>24 information.</p> <p>25 Q. Where do you get your relevant clinical</p>
<p style="text-align: right;">Page 19</p> <p>1 A. That's an interesting question, because my --</p> <p>2 Q. Thank you.</p> <p>3 A. -- my training background as OB-GYN resident</p> <p>4 at that time when I was in China. So after I came to</p> <p>5 United States, I think I liked to do more</p> <p>6 academic-related work. Therefore, pathology gives me a</p> <p>7 better opportunity to do both clinical care, patient</p> <p>8 care, as well as research.</p> <p>9 And then after pathology training, in</p> <p>10 relation to my OB-GYN training, so it's very natural to</p> <p>11 put them together to do GYN pathology and become a</p> <p>12 specialist.</p> <p>13 Q. It made sense to combine them?</p> <p>14 A. Right, right.</p> <p>15 Q. And there are different areas of pathology,</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And what is the area that you consider</p> <p>19 yourself in? Not the specialty area, but surgical</p> <p>20 pathology or experimental pathology, laboratory</p> <p>21 pathology? I'm not sure I'm getting those right, but</p> <p>22 what do you consider yourself?</p> <p>23 MR. SNELL: Form.</p> <p>24 Go ahead.</p> <p>25 A. Basically within the pathology field, like GYN</p>	<p style="text-align: right;">Page 21</p> <p>1 information?</p> <p>2 A. Typically these information will be written on</p> <p>3 the requisition sheet, and then some of them through</p> <p>4 communication with the clinicians. And like a special</p> <p>5 form, like a tumor board, is one of the common forms to</p> <p>6 take care of cancer patients.</p> <p>7 Q. So when a specimen comes from the operating</p> <p>8 room, it is accompanied with a requisition form, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And that requisition form has a diagnosis or a</p> <p>11 tentative diagnosis when it comes to you, correct?</p> <p>12 A. No. They will contain relevant clinical</p> <p>13 information, basic information for the patients, and</p> <p>14 clinical observations. They usually do not have a</p> <p>15 typical diagnosis in the clinical requisition sheet,</p> <p>16 because otherwise why they need a pathologist to help</p> <p>17 them?</p> <p>18 They have questions whether this may</p> <p>19 represent some kind of disease or what kind of particular</p> <p>20 area they try to resolve. Then usually they have</p> <p>21 limitation from clinical perspective. They can't resolve</p> <p>22 that. That's why they need a pathologist's opinion to</p> <p>23 give them more definitive answers for that.</p> <p>24 Q. But isn't it true that every surgical specimen</p> <p>25 comes to you regardless of whether the doctor had a</p>

<p style="text-align: right;">Page 22</p> <p>1 question about the diagnosis or not?</p> <p>2 A. Correct. Many of them they don't have the</p> <p>3 diagnosis. They just give you a specimen, tell you the</p> <p>4 clinical problem. Then you will help them.</p> <p>5 Q. So a clinical problem could be a symptom?</p> <p>6 A. Right.</p> <p>7 Q. Like pain or -- correct?</p> <p>8 A. Yes. Pain or bleeding or, you know,</p> <p>9 abnormal -- any kind of abnormalities.</p> <p>10 Q. But at times, at least, the surgeon knows what</p> <p>11 the diagnosis is and is just sending you -- sending the</p> <p>12 specimen to you for confirmation; is that correct?</p> <p>13 MR. SNELL: Form.</p> <p>14 A. That's not true, because they -- for instance,</p> <p>15 they may suspect the patient may have a cancer, right?</p> <p>16 But a cancer diagnosis has lots of other specific</p> <p>17 information, such as cancer grade, cancer type, primary</p> <p>18 sites of the cancers.</p> <p>19 So lots of information may be relevant to</p> <p>20 future clinical decision for the management. They don't</p> <p>21 know at that time. Therefore, you need a pathologist to</p> <p>22 give -- to provide such information.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. But if you have a uterus that the surgeon is</p> <p>25 sending you for fibroids --</p>	<p style="text-align: right;">Page 24</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Yeah. I got one in.</p> <p>3 A. Okay.</p> <p>4 Q. Fair enough. And pathologists generally don't</p> <p>5 perform your own complete chart review; is that correct?</p> <p>6 A. In the usual situation, we do not review those</p> <p>7 complete medical records.</p> <p>8 Q. Would you agree with the statement that the</p> <p>9 pathologist's interpretation is based on his</p> <p>10 understanding of the clinical context and resulting</p> <p>11 questions to be answered?</p> <p>12 A. Yes. That's a good statement.</p> <p>13 Q. I think that's basically what we just said,</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. How many mesh specimens have you evaluated?</p> <p>17 A. So far?</p> <p>18 Q. So far.</p> <p>19 A. Within basically I think around three years,</p> <p>20 around three years, I start to see more mesh specimens</p> <p>21 coming. So overall I can estimate it's about maybe more</p> <p>22 than a hundred cases I have examined in total.</p> <p>23 Q. And I think in the Lewis deposition in</p> <p>24 December, you said it was somewhere between 156 and 312.</p> <p>25 There was some discussion about how you came up with</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Yes.</p> <p>2 Q. -- chances are it's going to have fibroids,</p> <p>3 correct?</p> <p>4 MR. SNELL: Form.</p> <p>5 A. Correct. But also there are chances for</p> <p>6 nonfibroid or even it's a malignant cancer or metastatic</p> <p>7 cancer to the uterus. So, therefore, they are not sure.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. Fair enough. When surgeons, GYN surgeons do</p> <p>10 vaginal repair surgery and remove part of the vaginal</p> <p>11 mucosa, as in an anterior colporrhaphy, do you get that</p> <p>12 specimen?</p> <p>13 A. Yes. We usually get -- those repair</p> <p>14 surgeries, we get specimens like just the vaginal mucosa,</p> <p>15 sort of redundancy vaginal mucosa, and we will evaluate</p> <p>16 that.</p> <p>17 Q. Do you look at those histologically or not?</p> <p>18 A. Yes. We do every time.</p> <p>19 Q. Okay. But that would be one example of a case</p> <p>20 where the doctor really isn't looking to you for a</p> <p>21 diagnosis of redundant vaginal mucosa, right?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. Right. Those are -- usually there is not much</p> <p>24 abnormality there.</p> <p>25</p>	<p style="text-align: right;">Page 25</p> <p>1 those numbers.</p> <p>2 Are you -- now can you give a better</p> <p>3 estimate that it's --</p> <p>4 A. I said basically you can see every week I</p> <p>5 receive like one to two samples of these mesh specimens.</p> <p>6 And then if you have 50 weeks in a year, then it's</p> <p>7 already 50 to 100 cases. So the minimum is about maybe</p> <p>8 just over a hundred. The maximum can go as more as you</p> <p>9 can go, like 300. I think that's -- but I just really</p> <p>10 don't know the exact number.</p> <p>11 Q. What are the usual -- what are the most common</p> <p>12 indications for mesh removal that you see?</p> <p>13 A. We have mesh -- like prolapse mesh</p> <p>14 complications, such as infection or erosion. Or</p> <p>15 sometimes a patient chart or requisition sheet will list</p> <p>16 pain. Those are -- and then also these days more</p> <p>17 commonly is for legal purpose without any symptoms. It</p> <p>18 says the specimen is for legal purpose.</p> <p>19 Q. So you are telling me that you're getting</p> <p>20 specimens that the reason they're having their mesh</p> <p>21 removed is for legal purposes?</p> <p>22 A. Many of them.</p> <p>23 Q. What percentage would you say that is?</p> <p>24 A. I think these days probably over 50 percent at</p> <p>25 least.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. And that's over what period of time?</p> <p>2 A. It's particularly within the last two years'</p> <p>3 period.</p> <p>4 MS. THOMPSON: And I'm going to, of</p> <p>5 course, request the records on those meshes that he's</p> <p>6 evaluated over the last three years.</p> <p>7 MR. SNELL: We're not going to produce</p> <p>8 those. Those are his own patients. That's hospital</p> <p>9 stuff.</p> <p>10 MS. THOMPSON: Okay. Then we'll take back</p> <p>11 Dr. Iakovlev's that he did with redacted information, but</p> <p>12 we'll discuss that.</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. And what do you mean by remove for legal</p> <p>15 purposes?</p> <p>16 A. When we receive the specimen, then as we</p> <p>17 mentioned typically there is a requisition sheet. And</p> <p>18 within the requisition sheet, clinical history, and then</p> <p>19 they will say for legal purpose.</p> <p>20 And those specimens we have a special way</p> <p>21 to handle, because typically if the specimen is large</p> <p>22 enough, we will take a portion of the specimen for</p> <p>23 routine process. Then the remaining portion we'll submit</p> <p>24 to our legal office. Within our medical center, we have</p> <p>25 a special office to handle all the potential legal</p>	<p style="text-align: right;">Page 28</p> <p>1 A. I think, based on my understanding, at least</p> <p>2 some of those cases, yes, definitely go that way.</p> <p>3 Q. Who are the doctors that are doing that in</p> <p>4 your facility?</p> <p>5 A. We have Christian Twiss, T-W-I-S-S, and also,</p> <p>6 Dr. Hatch, Kenneth Hatch. These are the main doctors. A</p> <p>7 few other doctors occasionally have several other</p> <p>8 specimens, but these are the two main doctors.</p> <p>9 Q. And you believe that Dr. Twiss -- I'm not</p> <p>10 pronouncing their names correctly, I'm sure -- and Dr.</p> <p>11 Hatch are removing mesh at the request of lawyers?</p> <p>12 A. Because it's written clearly in the</p> <p>13 requisition sheet.</p> <p>14 Q. You mentioned prolapse mesh. How many...</p> <p>15 So you, I think, said just a minute ago</p> <p>16 that all surgery has a reason. Do you consider legal</p> <p>17 purposes a reason for surgery --</p> <p>18 MR. SNELL: Form.</p> <p>19 (By Ms. Thompson)</p> <p>20 Q. -- in your experience as a pathologist and</p> <p>21 OB-GYN?</p> <p>22 A. I think so some of these cases because of the</p> <p>23 legal purpose for the surgery. Why, you know, the law</p> <p>24 office want them to have this surgery done, I have no</p> <p>25 idea.</p>
<p style="text-align: right;">Page 27</p> <p>1 purposes of all these cases.</p> <p>2 Q. But you're telling me these are not patients</p> <p>3 that have other symptoms and they're just wanting you to</p> <p>4 handle it in a particular way because of legal purposes,</p> <p>5 but that's the only reason that they're having the mesh</p> <p>6 removed?</p> <p>7 A. I'm not sure, because they usually do not put</p> <p>8 what kind of underlining reason for legal purposes.</p> <p>9 Q. And would you agree with me that it would be</p> <p>10 medical malpractice for a surgeon to have a patient</p> <p>11 undergo major surgery and general anesthesia for no</p> <p>12 reason?</p> <p>13 MR. SNELL: Form.</p> <p>14 A. Yeah. Typically any surgery there is a</p> <p>15 reason, typically. But I do have seen those mesh, you</p> <p>16 know, specimens without any complaints, and basically the</p> <p>17 doctors -- we have -- our clinicians sometimes we</p> <p>18 communicate these days. They also noticed many requests</p> <p>19 direct the patient see them because some law office call</p> <p>20 them and say, Can you go to, you know, certain medical</p> <p>21 office to get this mesh removed?</p> <p>22 (By Ms. Thompson)</p> <p>23 Q. So you're saying that doctors are removing</p> <p>24 mesh because the lawyer sent a patient and asked them to</p> <p>25 remove the mesh?</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Would that not be considered unnecessary</p> <p>2 surgery, in quotations?</p> <p>3 MR. SNELL: Form.</p> <p>4 A. I'm not in the position to make this comment,</p> <p>5 because I'm in the position, whatever specimen come to</p> <p>6 our department, then we will provide opinion. That's my</p> <p>7 position, I think. What's the reason why they are going</p> <p>8 to do this, that will be beyond my, you know, ability to</p> <p>9 make judgment.</p> <p>10 MR. SNELL: And he has not been put up as</p> <p>11 a surgical expert on standard of care.</p> <p>12 MS. THOMPSON: Understand.</p> <p>13 MR. SNELL: We have urologists and</p> <p>14 urogynecologists who will opine on that.</p> <p>15 And I'll put one other thing on the</p> <p>16 record. Your request, the cases he has seen obviously</p> <p>17 are those that have arisen in the context of his normal</p> <p>18 duties and work as a pathologist.</p> <p>19 Dr. Iakovlev, on the other hand, testified</p> <p>20 that he has been sent numerous meshes from plaintiffs'</p> <p>21 lawyers and that he has been paid for his evaluations by</p> <p>22 those plaintiffs' lawyers, and he enters those plaintiff</p> <p>23 lawyer-sent meshes into his hospital system; thereby</p> <p>24 trying to create, apparently, some type of HIPAA issue.</p> <p>25 So there's crystal clear differences between Dr. Zheng</p>

<p style="text-align: right;">Page 30</p> <p>1 and Dr. Iakovlev.</p> <p>2 MS. THOMPSON: I believe you requested</p> <p>3 records from both the ones received from litigation and</p> <p>4 the ones that came through the hospital. But we can go</p> <p>5 back and look at that.</p> <p>6 MR. SNELL: We did not request medical</p> <p>7 records on patients who had nothing to do with</p> <p>8 litigation.</p> <p>9 MS. THOMPSON: And I'm not requesting --</p> <p>10 MS. FITZPATRICK: You did.</p> <p>11 MS. THOMPSON: You did.</p> <p>12 MS. FITZPATRICK: You should go back and</p> <p>13 look at Donna's letter which clearly requested everything</p> <p>14 that Dr. Iakovlev had looked at. And it was certainly</p> <p>15 not limited to what had been received from plaintiffs.</p> <p>16 So I don't think that we need to waste the time here.</p> <p>17 But that's completely inaccurate what you just said, so</p> <p>18 we'll put that on the record.</p> <p>19 MR. SNELL: And I believe you're being</p> <p>20 inaccurate. But whatever. So go ahead.</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. You mentioned with the prolapse meshes you see</p> <p>23 requisitions listing infection, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And erosion, correct?</p>	<p style="text-align: right;">Page 32</p> <p>1 I assume you have that.</p> <p>2 (Marked for Identification:</p> <p>3 Deposition Exhibit No. 1)</p> <p>4 MR. SNELL: Can I get a copy, please?</p> <p>5 MS. THOMPSON: I thought you would have</p> <p>6 one, so I just did two of those.</p> <p>7 Actually, oh, I do have three.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. Have you seen this document before, Dr. Zheng?</p> <p>10 A. I think I have seen this kind of document,</p> <p>11 yes.</p> <p>12 Q. I'm talking about this particular document</p> <p>13 have you seen?</p> <p>14 A. Oh. I don't remember to see this particular</p> <p>15 document.</p> <p>16 Q. What did you do to prepare for the deposition</p> <p>17 today?</p> <p>18 A. What did I do for the -- for this deposition?</p> <p>19 Q. Yes.</p> <p>20 A. I reviewed my report. I received instruction</p> <p>21 from Ethicon lawyers to bring all the material, whatever</p> <p>22 I have I can dig out for the case. Then even including</p> <p>23 some of the references I used for Lewis case. So I</p> <p>24 brought everything here.</p> <p>25 Q. And where are the materials that you brought?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Yes.</p> <p>2 Q. And pain, correct?</p> <p>3 A. Correct.</p> <p>4 Q. What percentage of your mesh cases that you</p> <p>5 receive in your lab are slings and not prolapse mesh?</p> <p>6 A. These days I think more than prolapse.</p> <p>7 Overall how many exactly, I have no idea. But majority</p> <p>8 of the meshes these days are slings.</p> <p>9 Q. And you mentioned the number that have listed</p> <p>10 on their requisition the reason for surgery or the reason</p> <p>11 for pathological evaluation is legal purposes. What</p> <p>12 about the others? What are the most common symptoms or</p> <p>13 complications listed for slings?</p> <p>14 A. I don't have any statistics for that. But</p> <p>15 those are quite common. Which one is the most common, I</p> <p>16 don't know. I can't give you that accurate information.</p> <p>17 Q. Would you say it would also be the same as for</p> <p>18 prolapse: Infection, erosion and pain?</p> <p>19 A. Many of the sling specimens they do not</p> <p>20 provide specific information. Some of them they do, but</p> <p>21 a majority of them no information except for legal</p> <p>22 purposes. And just -- or sometimes just says suburethral</p> <p>23 sling, that's it.</p> <p>24 MS. THOMPSON: I'll go ahead and mark</p> <p>25 Dr. Zheng's notice as Exhibit 1.</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Those are the materials. Boxes of these</p> <p>2 material.</p> <p>3 Q. Oh, okay.</p> <p>4 A. See them?</p> <p>5 MS. THOMPSON: So I guess we'll -- where</p> <p>6 are the boxes?</p> <p>7 MR. SNELL: There's multiple boxes over</p> <p>8 there --</p> <p>9 MS. THOMPSON: Oh, the boxes on the cart?</p> <p>10 MR. SNELL: -- and a hanging bag.</p> <p>11 MS. THOMPSON: I guess we will mark those</p> <p>12 boxes as Exhibit 2, and we'll go through them at some</p> <p>13 point during the day, but --</p> <p>14 MR. SNELL: Here, I'll let you give that</p> <p>15 to her, too. That's your stuff.</p> <p>16 MS. THOMPSON: John, do you want to put</p> <p>17 that on the boxes?</p> <p>18 MR. FABRY: Can we go off the record for a</p> <p>19 second?</p> <p>20 THE VIDEOGRAPHER: Off the record 10:45.</p> <p>21 (Discussion held off the record.)</p> <p>22 THE VIDEOGRAPHER: On the record 10:46.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. Dr. Zheng, you brought several boxes with you</p> <p>25 in response to this -- what your lawyers told you to</p>

<p style="text-align: right;">Page 34</p> <p>1 bring, everything, I guess, related to this case; is that</p> <p>2 correct?</p> <p>3 A. Correct.</p> <p>4 MR. SNELL: Form.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. And do you have those materials in an</p> <p>7 electronic form as well?</p> <p>8 A. I don't believe I have everything, but I do</p> <p>9 have several, I think, discs or so. But I'm not sure.</p> <p>10 Some of these discs containing medical records informa-</p> <p>11 tion and may have not completely or complete information</p> <p>12 for everything I have. So that's the situation.</p> <p>13 But many of them, either medical records</p> <p>14 or references I used, I read and then piled them up in a</p> <p>15 binder. Okay? Then also these are the relevant</p> <p>16 information, like expert's report from Dr. Pramudji</p> <p>17 regarding Huskey case. And then the other one is expert</p> <p>18 report from Elizabeth Kavalier. I don't know how to</p> <p>19 pronounce that correctly. But those are the -- I have</p> <p>20 read.</p> <p>21 And many of these references regarding TVT</p> <p>22 mesh or TVT-O or TOT mesh. And then I also printed out</p> <p>23 the pictures in a raw form. Basically all these pictures</p> <p>24 I took from the slides I received, I reviewed, for the</p> <p>25 purpose of to present my points. And I think many of</p>	<p style="text-align: right;">Page 36</p> <p>1 record just so we're clear. The electronic files and the</p> <p>2 discs and CDs, he has brought those, too. They're in</p> <p>3 that hanging bag. There are multiple CDs over there with</p> <p>4 all the electronic files.</p> <p>5 MS. FITZPATRICK: Can we have those?</p> <p>6 MR. SNELL: No. Those are his originals.</p> <p>7 MS. FITZPATRICK: Okay. We'll go through</p> <p>8 them at a break and figure it out.</p> <p>9 THE WITNESS: You can take a look at</p> <p>10 whatever you feel like.</p> <p>11 MS. THOMPSON: Okay. I'll put that on the</p> <p>12 box, I guess, and we'll look at everything at a break.</p> <p>13 THE WITNESS: Okay.</p> <p>14 (Marked for Identification:</p> <p>15 Deposition Exhibit No. 2)</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. Did you meet with the lawyers in preparation</p> <p>18 for the deposition?</p> <p>19 A. I think yesterday, Andy, yes, I met Andy in my</p> <p>20 office.</p> <p>21 Q. And when was that?</p> <p>22 A. That's yesterday morning.</p> <p>23 Q. For how long?</p> <p>24 A. About two hours.</p> <p>25 Q. And what did you review during that meeting?</p>
<p style="text-align: right;">Page 35</p> <p>1 them -- some of them I constructed those pictures into a</p> <p>2 PPT form so make people can understand it better.</p> <p>3 Otherwise these loose individual pictures without the</p> <p>4 text makes everybody feel difficult. That's the</p> <p>5 combination. I have those PPT PowerPoint also printed.</p> <p>6 That's for everybody's convenience, basically. Those are</p> <p>7 the things. Later on you may examine that.</p> <p>8 Q. So that smaller box that you've brought with</p> <p>9 you are articles that you relied upon, correct?</p> <p>10 A. Yeah. Many of them I read and then relied</p> <p>11 upon, that's true.</p> <p>12 Q. And two reports of the defense experts in this</p> <p>13 case, Dr. Kavalier and Dr. Pramudji, correct?</p> <p>14 A. Yeah. Those -- I think these two clinicians'</p> <p>15 expert report I have just read, because before I wrote my</p> <p>16 expert report, I was not aware of this. That's okay.</p> <p>17 Q. So you did not rely on those two expert</p> <p>18 reports for any of the opinions in your --</p> <p>19 A. Correct.</p> <p>20 Q. -- own report, correct?</p> <p>21 A. Within the report.</p> <p>22 MS. THOMPSON: Let's go ahead and mark</p> <p>23 your box as Exhibit 2.</p> <p>24 THE WITNESS: Okay.</p> <p>25 MR. SNELL: I want to put something on the</p>	<p style="text-align: right;">Page 37</p> <p>1 A. So basically we reviewed my expert report to</p> <p>2 see do I have any questions are not clear for the case.</p> <p>3 I think those are the procedures. Then we went through</p> <p>4 the pictures or the stuff I printed out, those pictures.</p> <p>5 Just went through these pictures. It takes a long time</p> <p>6 for the pictures.</p> <p>7 Q. Is that all?</p> <p>8 A. Yeah, I think that's it.</p> <p>9 Q. And have you met with the lawyers prior to</p> <p>10 meeting yesterday with Andy?</p> <p>11 A. Prior to yesterday, you mean?</p> <p>12 Q. Correct.</p> <p>13 A. I think some times ago Andy -- no, I don't</p> <p>14 think we have other meetings, because we know each other.</p> <p>15 And I received multiple -- we have several phone calls.</p> <p>16 And then when I receive material, if I'm not clear what</p> <p>17 are they, then I call him to clarify.</p> <p>18 Q. So how do you know Andy?</p> <p>19 A. For the Lewis case, I think.</p> <p>20 Q. So you worked with him on the Lewis case?</p> <p>21 A. The Lewis case, too, correct.</p> <p>22 Q. How much have you been paid by Ethicon to</p> <p>23 serve as an expert witness?</p> <p>24 A. I -- I have received maybe, let's see, \$50,000</p> <p>25 before the tax. That's so far for the Lewis case.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. And how much for the Huskey and Edwards cases</p> <p>2 so far?</p> <p>3 A. So far I did not bill yet.</p> <p>4 Q. Can you estimate how many hours you have</p> <p>5 spent?</p> <p>6 A. It's roughly about 40 to 50 hours I have spent</p> <p>7 so far.</p> <p>8 Q. And how much do you charge per hour?</p> <p>9 A. Six hundred dollar per hour.</p> <p>10 Q. And is that for any kind of work or is it --</p> <p>11 A. Yeah. For all these readings and evaluation</p> <p>12 of reports and review for like the deposition issues or</p> <p>13 court issues usually or travel is up to 10 hours. I</p> <p>14 can't charge when I sleep.</p> <p>15 Q. I think that's a good rule.</p> <p>16 A. Okay.</p> <p>17 Q. Although we all know people that do. I didn't</p> <p>18 say that.</p> <p>19 So you -- did you bring all the photos --</p> <p>20 all right. So let me go back. Looking at Schedule A on</p> <p>21 that notice of deposition, which is the list of all the</p> <p>22 things to bring -- do you have that with you, Dr. Zheng?</p> <p>23 It's page 3.</p> <p>24 A. Page 3.</p> <p>25 Q. So you're saying that what you've produced</p>	<p style="text-align: right;">Page 40</p> <p>1 on Ms. Edwards?</p> <p>2 A. Some of the -- yeah. Some of the opinions</p> <p>3 rely on based on my experience, that's true.</p> <p>4 Q. And you would expect --</p> <p>5 A. Sure.</p> <p>6 Q. -- anyone's experience to help them when</p> <p>7 they're formulating opinion on a similar case, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Did you bring photos of the other mesh cases</p> <p>10 that you've seen over the last three years?</p> <p>11 A. No. It's not related to these two patients.</p> <p>12 MS. THOMPSON: We're going to request all</p> <p>13 the photographs that you have taken on any mesh cases</p> <p>14 over the past three years.</p> <p>15 MR. SNELL: And we'll oppose.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: I have --</p> <p>18 MR. SNELL: Those are --</p> <p>19 THE WITNESS: I usually do not take any,</p> <p>20 so --</p> <p>21 MR. SNELL: Those are his hospital</p> <p>22 patients, not litigation, lawyer-referred cases for which</p> <p>23 he has been paid by lawyers. Go ahead.</p> <p>24 MS. THOMPSON: And you requested from us</p> <p>25 and we provided all the photos taken by Dr. Iakovlev</p>
<p style="text-align: right;">Page 39</p> <p>1 here is contained in this box, those boxes, and the discs</p> <p>2 that you brought, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Did you bring billing records?</p> <p>5 A. No. I sent -- send my billing records to my</p> <p>6 lawyer, but I did not bring this time.</p> <p>7 MS. THOMPSON: Do we have billing records</p> <p>8 for Dr. Zheng?</p> <p>9 MR. SNELL: I think we have a summary of</p> <p>10 invoices.</p> <p>11 Do we have a summary of invoices or some</p> <p>12 type of tally?</p> <p>13 MR. SNOWDEN: Yeah. We can print it off.</p> <p>14 MR. SNELL: Yeah. We'll print it off.</p> <p>15 MS. THOMPSON: Yeah, we would like to have</p> <p>16 that.</p> <p>17 MR. SNELL: Okay.</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. Looking at number -- until we -- we may come</p> <p>20 back to this after we've had a chance to look through</p> <p>21 some of the boxes.</p> <p>22 But going down to 11, does your experience</p> <p>23 with looking at over a hundred mesh cases over the last</p> <p>24 three years -- well, do you rely on your experience</p> <p>25 looking at other mesh cases in formulating your opinions</p>	<p style="text-align: right;">Page 41</p> <p>1 on all mesh, regardless of whether they were litigation</p> <p>2 or not. And Dr. Zheng has certainly been paid</p> <p>3 significantly for his work.</p> <p>4 MR. SNELL: Move to strike.</p> <p>5 Go ahead.</p> <p>6 THE WITNESS: Can I explain that?</p> <p>7 MR. SNELL: No. She didn't give you a</p> <p>8 question. She'll pose a question.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. So you did not bring any photos other than the</p> <p>11 ones on the slides that you took of Ms. Edwards, correct?</p> <p>12 A. What I want to say is, for my routine work, I</p> <p>13 do not take microphotographs for these other meshes,</p> <p>14 except somebody request us, you know, some kind of</p> <p>15 photographs. Then we provide. We don't take</p> <p>16 microphotographs.</p> <p>17 We have slides for every case that will be</p> <p>18 kept for 10 years, typically, in our hospital. Then the</p> <p>19 specimen, if it's not for legal purpose, will be throw</p> <p>20 away after the report -- after two weeks after the report</p> <p>21 is generated.</p> <p>22 MS. THOMPSON: We'll request the slides as</p> <p>23 well with patient information redacted.</p> <p>24 MR. SNELL: And we will oppose.</p> <p>25 Go ahead.</p>

<p style="text-align: right;">Page 42</p> <p>1 THE WITNESS: But I'm not sure I --</p> <p>2 MR. SNELL: You don't have to respond to</p> <p>3 that. She's making a request, and we will oppose it.</p> <p>4 Go ahead.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. And when you said that you only take pictures</p> <p>7 when it's requested, what do you mean by that?</p> <p>8 A. For instance, this Lewis case, if I have</p> <p>9 slides, then I will take pictures, because I have to</p> <p>10 present my points or my opinion.</p> <p>11 And for this case, for Edwards case, also</p> <p>12 I have multiple slides. So when I review that, then I</p> <p>13 have to present my opinion based on what I have observed.</p> <p>14 Therefore, the pictures are useful. So then at that time</p> <p>15 I take pictures.</p> <p>16 Q. Have you ever lectured or presented on the</p> <p>17 topic of GYN mesh, either in your hospital or your</p> <p>18 division or elsewhere?</p> <p>19 A. No.</p> <p>20 Q. Never lectured to medical students about mesh</p> <p>21 and its properties?</p> <p>22 A. I will briefly mention those. Those can be</p> <p>23 specimens we routinely received. But that's it. We</p> <p>24 don't go that far, because medical students usually they</p> <p>25 are not interested in this kind of topic. They have too</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Uh-huh.</p> <p>2 Q. You have never published anything on</p> <p>3 polypropylene mesh; is that correct?</p> <p>4 A. Correct.</p> <p>5 Q. And I believe you just told me that you have</p> <p>6 not lectured on mesh?</p> <p>7 A. Correct.</p> <p>8 Q. Did you issue a pathology report on</p> <p>9 Ms. Edwards?</p> <p>10 A. No. Because these slides came for review</p> <p>11 consultation, not in our medical system.</p> <p>12 Q. Who wrote your expert report?</p> <p>13 A. I wrote by myself.</p> <p>14 Q. What are the indications for mesh removal, in</p> <p>15 your opinion?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. Indications typically for mesh removal, based</p> <p>18 on my understanding, for medical purposes is like</p> <p>19 erosion, infection, or constant pain exceed usual level</p> <p>20 than patient cannot tolerate and possibly related to the</p> <p>21 mesh. Therefore, those are the more common medical</p> <p>22 reasons for the removal.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. Does mesh cause constant pain that can't be</p> <p>25 relieved?</p>
<p style="text-align: right;">Page 43</p> <p>1 much to learn.</p> <p>2 Q. What about to OB-GYN residents or -- how about</p> <p>3 to OB-GYN residents?</p> <p>4 A. OB-GYN residents, usually these are mainly</p> <p>5 clinical side knowledge or diseases or situations. So it</p> <p>6 will be given by the clinicians rather than pathologists.</p> <p>7 Q. Do OB-GYN residents do a rotation through the</p> <p>8 pathology department?</p> <p>9 A. Usually they don't. But we do have two kinds</p> <p>10 of weekly conferences. One is in the Wednesday morning.</p> <p>11 Then depending on the topic, our pathologists will join</p> <p>12 their conference to present pathology component. And</p> <p>13 then the other conference, the GYN tumor board, that</p> <p>14 requires multispecialty, you know, doctors to join it.</p> <p>15 Q. And mesh has never been a topic for the weekly</p> <p>16 conferences, joint conferences?</p> <p>17 A. No. Mesh has never been a formal topic for</p> <p>18 education purpose.</p> <p>19 Q. When were you first contacted by Ethicon?</p> <p>20 A. I think probably that's at the end of two</p> <p>21 years ago, 2012 something.</p> <p>22 Q. And what case did they consult you on</p> <p>23 initially?</p> <p>24 A. That's the Lewis case.</p> <p>25 Q. The Lewis case?</p>	<p style="text-align: right;">Page 45</p> <p>1 A. Pain is a complicated situation, because that</p> <p>2 involves multiple reasons. So it's very hard to say,</p> <p>3 because in the -- in our OB-GYN practice, we have</p> <p>4 patients complain of pelvic pain. That's very common.</p> <p>5 Even without mesh they have those symptoms.</p> <p>6 And then among those pelvic-pain patients,</p> <p>7 we have like 50 percent of those cases we have evidence</p> <p>8 to support there is a reason to explain pain. However,</p> <p>9 additional 50, half of the patients, have no histological</p> <p>10 evidence to support. So it's difficult to interpret why</p> <p>11 the patient feel pain.</p> <p>12 Q. I'll ask my question again. Can mesh cause</p> <p>13 pain that is constant and can't be relieved?</p> <p>14 MR. SNELL: Objection. Form. Asked and</p> <p>15 answered. And beyond the scope if you're asking him from</p> <p>16 a surgeon's perspective. He's only here on the pathology.</p> <p>17 MS. THOMPSON: He told me that he got</p> <p>18 requisitions for mesh removal that stated it was from</p> <p>19 patients who had constant pain that could not be</p> <p>20 relieved.</p> <p>21 MR. SNELL: That's fine. That's what he</p> <p>22 got as a pathologist.</p> <p>23 MS. THOMPSON: I'm asking if mesh can</p> <p>24 cause that pain. I believe that would be what a</p> <p>25 pathologist would tell the surgeon.</p>

<p style="text-align: right;">Page 46</p> <p>1 A. The pathologists provide pathology report.</p> <p>2 They usually do not provide a statement says the finding</p> <p>3 can explain the clinical pain. There is no -- usually do</p> <p>4 not do that, except obvious evidence. For instance,</p> <p>5 there is like infection, abscess formation there.</p> <p>6 And then the doctor clinician will ask, Do</p> <p>7 you think this abscess may be related to her pain? This</p> <p>8 is obvious I say usually. You don't have to say this</p> <p>9 particularly the findings are related to the clinical</p> <p>10 pain. They can use the findings to interpret by</p> <p>11 themself.</p> <p>12 Because, as I say, pain is a very</p> <p>13 complicated situation. It's a personal feeling. Some of</p> <p>14 these pain can have a reason to explain. Some of those</p> <p>15 pain do not have a reason to explain.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. So you're telling me that as a pathologist you</p> <p>18 are not able to tell whether a patient having pain and</p> <p>19 you receive a mesh specimen, whether it's related to the</p> <p>20 pain or not?</p> <p>21 A. Correct. But let me add something. But if</p> <p>22 the histological evidence or pathological evidence is</p> <p>23 obvious, then that can be consistent with the clinical</p> <p>24 symptoms such as pain. If there's no, you know, evidence</p> <p>25 to support, then usually there's no linkage between the</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. SNELL: This was marked as 3?</p> <p>2 THE WITNESS: Uh-huh, yes.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. So you have seen this article?</p> <p>5 A. Yes. I think I noticed the title sounds</p> <p>6 familiar.</p> <p>7 Q. And I would think it would be of interest to</p> <p>8 you as a GYN pathologist that's looking at mesh, correct?</p> <p>9 A. Yes.</p> <p>10 Q. We can just look in the abstract under</p> <p>11 results. And could you just read the third sentence</p> <p>12 there that begins with, Specimen requisitions.</p> <p>13 A. Specimen requisitions listed clinical history</p> <p>14 as pain, 28.4 percent; vaginal mesh erosion,</p> <p>15 24.5 percent; then erosion, 17.6 percent; then urinary</p> <p>16 retention 5.9 percent; and infection, 2.9 percent.</p> <p>17 Q. So at least in -- at the University of</p> <p>18 Michigan, the surgeons filling out requisitions for</p> <p>19 pathologic examination of mesh specimens that they</p> <p>20 removed from women thought that these patients' pain was</p> <p>21 coming from the mesh, correct?</p> <p>22 MR. SNELL: Form, foundation.</p> <p>23 A. Yeah. Based on clinical symptoms or clinical</p> <p>24 information as listed.</p> <p>25</p>
<p style="text-align: right;">Page 47</p> <p>1 finding -- pathological finding and the clinical pain.</p> <p>2 Q. As in an abscess?</p> <p>3 A. Right.</p> <p>4 Q. Are you aware that in the published literature</p> <p>5 on explanted vaginal mesh that the most common indication</p> <p>6 is pain?</p> <p>7 MR. SNELL: I'm going to object to the</p> <p>8 form on that one, and I'm going to object to the</p> <p>9 foundation on that one as well.</p> <p>10 Go ahead.</p> <p>11 A. I'm not aware of such particular publications</p> <p>12 saying the most common reason for mesh removal is pain.</p> <p>13 MS. THOMPSON: I'll go ahead and mark an</p> <p>14 exhibit. Are we on Number 3? Exhibit Number 3. And I</p> <p>15 apologize for the highlights on this article, but it's</p> <p>16 color copied, and they showed up.</p> <p>17 Hang on. Thank you. Sorry about that.</p> <p>18 (Marked for Identification:</p> <p>19 Deposition Exhibit No. 3)</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. I just handed you an article published by the</p> <p>22 pathology group at Michigan. Are you familiar with that</p> <p>23 group?</p> <p>24 A. I'm not familiar with that group, but I think</p> <p>25 I have seen this article.</p>	<p style="text-align: right;">Page 49</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Okay. Beginning from when a specimen leaves</p> <p>3 the operating room and comes to your lab, can you go</p> <p>4 through that process with me step by step?</p> <p>5 A. Okay. So after the surgeon remove the</p> <p>6 specimen or remove the part of the organ or tissues, then</p> <p>7 these tissues have two forms situation. One is just as a</p> <p>8 fresh tissue coming to pathology lab. The other is they</p> <p>9 put the tissue into formalin for the preservation issue.</p> <p>10 Then we receive these either fresh or the specimen in</p> <p>11 formalin, two kinds.</p> <p>12 Q. And is -- I assume that someone has observed</p> <p>13 the gross specimen before it's placed in formalin or --</p> <p>14 A. No.</p> <p>15 Q. -- processed?</p> <p>16 A. No. Usually the surgeons just by themselves or</p> <p>17 the nurse in the OR, they will put the specimen into</p> <p>18 formalin or just fresh, these two different conditions.</p> <p>19 So when we receive those specimens, then from pathology</p> <p>20 point of view, we will record patient information. Then</p> <p>21 we have to label the specimen and assign a case number.</p> <p>22 Then they will be recorded in the system first.</p> <p>23 Then afterwards our residents or PA start</p> <p>24 to so-called gross examination of the specimen, describe</p> <p>25 what kind of specimen we received. Those including the</p>

<p style="text-align: right;">Page 50</p> <p>1 size and the shape and even sometimes the weight of the</p> <p>2 specimen and then texture or particular features of the</p> <p>3 specimen.</p> <p>4 Q. So in your facility, at least, the residents</p> <p>5 or a PA describes the gross appearance?</p> <p>6 A. The usual situation.</p> <p>7 Q. And then it goes to the next step?</p> <p>8 A. Then after so-called gross -- during the gross</p> <p>9 time, then the residents or PA will take representative</p> <p>10 sections, or some of them, if the sample is small enough,</p> <p>11 they will submit everything for microscopic examination.</p> <p>12 Q. And when the residents submit it for</p> <p>13 microscopic examination, they are putting it in a</p> <p>14 paraffin block; is that correct?</p> <p>15 A. Then the tissues will go through a tissue</p> <p>16 processor so-called, a tissue processor which convert</p> <p>17 gross specimen into a paraffin block. That takes also</p> <p>18 long time.</p> <p>19 Q. And that's called what again?</p> <p>20 A. Tissue processor.</p> <p>21 Q. Tissue processor?</p> <p>22 A. Yeah.</p> <p>23 Q. So the resident, him- or herself, is not</p> <p>24 actually putting the specimen into paraffin? That's done</p> <p>25 by a processor, by a machine?</p>	<p style="text-align: right;">Page 52</p> <p>1 we have to show like the length and the thickness of the</p> <p>2 tissue sections to try to expose the most -- potentially</p> <p>3 most interesting area later on will be showed on the</p> <p>4 slides, so there are a few rules there. But in general,</p> <p>5 yes, just put into cassette.</p> <p>6 Q. And then the tissue processor, is it -- am I</p> <p>7 correct that the tissue processor, in laymen's terms,</p> <p>8 just dips the cassette into the paraffin, into the liquid</p> <p>9 paraffin?</p> <p>10 A. No. The tissue processor is basically a</p> <p>11 so-called fixation and dehydration process. So that</p> <p>12 means it makes the tissue fixed, number one. And</p> <p>13 meanwhile in this process also excessive water amount</p> <p>14 within the tissue or cells will be removed, because these</p> <p>15 waters cause artifact. It makes tissue very difficult to</p> <p>16 cut. So the water amount have to be removed.</p> <p>17 Q. Okay.</p> <p>18 A. So that's the overall purpose for tissue</p> <p>19 processor.</p> <p>20 Q. So there are steps involved, correct?</p> <p>21 A. Multiple steps.</p> <p>22 Q. And typically you would not see a specimen</p> <p>23 until it's already been sectioned and placed on slides,</p> <p>24 correct?</p> <p>25 A. Then I should add additional one. When I see</p>
<p style="text-align: right;">Page 51</p> <p>1 A. They have to take the sample and put into</p> <p>2 cassette, a plastic cassette. The cassette is labeled</p> <p>3 with particular patient information. For this situation</p> <p>4 it's a case number, basically.</p> <p>5 Then these cassettes containing tissues</p> <p>6 will be put into the tissue processor. Then the tissue</p> <p>7 processor automatically runs including lots of chemicals</p> <p>8 there to make the tissues easy to be cut. Otherwise the</p> <p>9 fresh tissue is difficult to cut.</p> <p>10 Q. Okay. So let me go back, because I'm trying</p> <p>11 to understand this.</p> <p>12 A. Sure.</p> <p>13 Q. I missed my pathology rotation when I was out</p> <p>14 on maternity leave.</p> <p>15 So the resident puts the sample, either</p> <p>16 the whole specimen or a sample based on the size, into a</p> <p>17 cassette?</p> <p>18 A. Correct.</p> <p>19 Q. And I assume they just drop it in the</p> <p>20 cassette; is that correct?</p> <p>21 A. Yeah. They -- yes. They put it in the</p> <p>22 cassette, correct.</p> <p>23 Q. They don't manipulate the specimen in any way</p> <p>24 when they're putting it in the cassette, do they?</p> <p>25 A. They have -- there are several rules, because</p>	<p style="text-align: right;">Page 53</p> <p>1 gross specimens in several conditions. One is the</p> <p>2 specimen is coming for intraoperative consultation.</p> <p>3 Immediately when they -- even before they remove out, I</p> <p>4 sometimes go to operating room and take a look. And then</p> <p>5 they are going to ask me, What do you think? What should</p> <p>6 I do for this? Then I will provide my opinion. All</p> <p>7 right? So-called intraoperative consultation.</p> <p>8 Then the second --</p> <p>9 Q. That would be like a frozen section, correct?</p> <p>10 A. Then the second --</p> <p>11 Q. Oh, that's the second one?</p> <p>12 A. -- one is the frozen section. Frozen section,</p> <p>13 they give you the specimen, then let you evaluate, give</p> <p>14 them the preliminary diagnosis immediately, basically</p> <p>15 within 20 minutes. So we will do frozen section</p> <p>16 evaluation.</p> <p>17 Q. And would you agree that typically those</p> <p>18 situations arise when the surgeon is trying to determine</p> <p>19 whether there's a malignancy or not --</p> <p>20 A. Right.</p> <p>21 Q. -- that could influence the surgery itself?</p> <p>22 A. Right. The extensiveness of the surgery.</p> <p>23 What shall we -- how far they can go.</p> <p>24 Q. Because typically, processed in the usual</p> <p>25 fashion, it would take two to three days to come out?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. Right. And patient will go back. They cannot 2 just open the abdomen and close, then next day open 3 again. They cannot do that. 4 Q. And what is done by residents in your teaching 5 hospital in other hospitals might be done by a pathology 6 technician or assistant; is that correct? 7 A. Yes. They usually do gross examination and 8 record what they have seen and what kind of section they 9 are taking. Then reading the microscopic slides together 10 with the attending. 11 For mesh issue, the same thing. They are 12 going to read together with me. Then if I have questions 13 at that time, will ask, and they will provide additional 14 information. 15 Q. So the pathologist in a typical community 16 hospital like yourself, except in the situations where 17 you're having an intraoperative examination or a frozen 18 section, would not see the specimen itself until the 19 slides are processed, correct? 20 MR. SNELL: Form. 21 A. Yeah. In usual situations, the attendings 22 will not see the specimen until the slides come out. But 23 in community hospitals, there is -- typically they do not 24 have residents, so the pathologist or the attending 25 pathologist, they have to gross the specimen by themself.</p>	<p style="text-align: right;">Page 56</p> <p>1 (By Ms. Thompson) 2 Q. When you get a mesh sample into your lab, you 3 usually don't know the name of the mesh, correct? 4 A. Usually we don't know, because they do not 5 label clearly. 6 Q. And would you agree with me that -- and by 7 that I mean the manufacturer of the mesh or the name of 8 that sling or prolapse mesh piece. 9 A. Correct. But occasionally they do mention TVT 10 sling. 11 Q. But if they mention TVT sling, would you know 12 whether that was a TVT Retropubic or a TVT Obturator or a 13 TVT Exact or a TVT Abbrevio or all the various different 14 permutations of TVT? 15 A. We don't know. 16 Q. So when you're looking at all the different -- 17 and I'm sure you've seen where TVT has just been used in 18 a generic context, like Kleenex, right, that could be 19 referring to a sling from another manufacturer, correct? 20 MR. SNELL: Form. 21 A. I think so. This is correct. 22 (By Ms. Thompson) 23 Q. And does that, not knowing the manufacturer of 24 the particular mesh that you're looking at, impede your 25 ability to observe and analyze the specimen?</p>
<p style="text-align: right;">Page 55</p> <p>1 So at that time they will see the specimen. 2 (By Ms. Thompson) 3 Q. Okay. So it's actually different in community 4 hospitals than in academics. You don't see it -- as a 5 professor, you don't see it until the slides are 6 processed, correct? 7 A. Usually we don't need to see until we are 8 asked. They say, okay, I don't know what to do for this. 9 Can you come? Okay, we will come. 10 Q. And it's my understanding that you see all the 11 mesh that's coming from a GYN surgeon, correct? 12 A. Yes. 13 Q. So you typically do not see hernia mesh 14 samples, abdominal wall hernia mesh samples? 15 A. I don't see that, because that belong to 16 general surgical practice. 17 Q. And that's because in an academic setting, you 18 have a specialty in GYN -- 19 A. We have subspecialty. 20 THE COURT REPORTER: Doctor, you need to 21 let her finish her question before you start your answer. 22 You're starting to overlap. 23 MS. THOMPSON: We're both doing that a 24 little bit, so we'll work on it together. 25</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Can you rephrase your question, please? 2 Q. Sure. That wasn't a very good question. 3 Does that make you less able to observe 4 and document your findings, the fact that you do not know 5 the manufacturer of the mesh? 6 A. No. Because in typical situation, we do not 7 pay attention what kind of mesh, which brand it is. We 8 only evaluate what's the pathological findings maybe 9 useful for clinical management. That's the thing we are 10 paying attention. 11 Q. In your experience, are -- I believe you -- 12 well, I'll start all over. 13 In your experience, do the characteristics 14 of polypropylene mesh, are they similar among various 15 products? 16 A. I think TVT sling from Ethicon has reasonably 17 unique features under microscope. 18 Q. And by TVT, do you mean TVT or TVT-O? 19 A. Doesn't matter which one. It's all 20 polypropylene mesh fibers. These are monofilament 21 fibers. And under microscope, typically one is white and 22 the other is blue. So, therefore, when we see that, it's 23 quite unique for TVT. 24 Q. So by the unique features, you meant the blue 25 coloration, right?</p>

<p style="text-align: right;">Page 58</p> <p>1 A. Blue color or the pattern. Usually the</p> <p>2 patterns, the microscopic pattern, they are sort of --</p> <p>3 it's very difficult to describe what kind of pattern.</p> <p>4 But when we see a lot, we know this is most likely coming</p> <p>5 from that.</p> <p>6 Q. As best you can, describe the pattern that</p> <p>7 you're referring to. The blue coloration I understand,</p> <p>8 but what's the pattern microscopically that --</p> <p>9 A. They have individual either parallel two mesh</p> <p>10 fibers or sometimes mesh knots forming, you know, knitted</p> <p>11 area. You have clusters of the mesh fiber. And then in</p> <p>12 between these mesh fibers, you see integrated tissue.</p> <p>13 Those are the typical patterns.</p> <p>14 Q. And are you suggesting that you don't see</p> <p>15 those same patterns with, say, a SPARC or a Monarc mesh?</p> <p>16 A. Frankly speaking, under microscope, I barely</p> <p>17 see different patterns or notice the particular related</p> <p>18 to different brand. That's the situation.</p> <p>19 Q. Let me make sure I understand. So you're</p> <p>20 saying you don't see different patterns between the</p> <p>21 different brands except for the blue coloration?</p> <p>22 MR. SNELL: Form.</p> <p>23 Go ahead.</p> <p>24 A. I mean, under microscope, I don't see many</p> <p>25 like dramatically different patterns as I just described.</p>	<p style="text-align: right;">Page 60</p> <p>1 MS. THOMPSON: Okay. I think we can go</p> <p>2 ahead and change the tape.</p> <p>3 THE VIDEOGRAPHER: Off the record 11:26.</p> <p>4 This concludes tape number one.</p> <p>5 (Recess taken.)</p> <p>6 THE VIDEOGRAPHER: On the record 11:43.</p> <p>7 This begins tape number two.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. Dr. Zheng, would you agree with me that an</p> <p>10 accurate report is necessary when you're looking at a</p> <p>11 pathology specimen?</p> <p>12 MR. SNELL: Form. Vague.</p> <p>13 A. I'm not sure I understand your question.</p> <p>14 (By Ms. Thompson)</p> <p>15 Q. Okay. It probably wasn't very good.</p> <p>16 It's important for you as a pathologist to</p> <p>17 be as accurate and thorough as possible, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And is the reason for that because what you</p> <p>20 find and document can actually impact a patient's care</p> <p>21 and treatment, correct?</p> <p>22 A. I think we should make, you know, the basic</p> <p>23 statement is the pathologist report all the points should</p> <p>24 be relevant to patient care. All right? Then if the</p> <p>25 details are more helpful for patient care, then all these</p>
<p style="text-align: right;">Page 59</p> <p>1 But if I see the mesh without the blue and white colors,</p> <p>2 then that may be related to other brand. Otherwise this</p> <p>3 is most likely coming from TVT Ethicon mesh.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. Were you aware that AMS, that produces SPARC</p> <p>6 and Monarc mesh, designed their mesh to be identical to</p> <p>7 TVT mesh?</p> <p>8 MR. SNELL: Foundation.</p> <p>9 A. Can you repeat again, please?</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Were you aware that AMS designed their mesh to</p> <p>12 be identical to TVT?</p> <p>13 MR. SNELL: Same objection.</p> <p>14 A. I'm not aware of this particular situation.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. But you can't today say that you would see</p> <p>17 anything differently under the microscope looking at a</p> <p>18 TVT versus an AMS mesh versus a Boston Scientific mesh if</p> <p>19 they're monofilament polypropylene?</p> <p>20 MR. SNELL: Form.</p> <p>21 Go ahead.</p> <p>22 A. I'm not able to, because, frankly speaking, I</p> <p>23 did not pay attention -- particular attention to try to</p> <p>24 tell the difference from which brand or where it is</p> <p>25 coming from.</p>	<p style="text-align: right;">Page 61</p> <p>1 points should be included in the report.</p> <p>2 And it's not as far as whatever you feel</p> <p>3 you find very, very detailed. But those detail</p> <p>4 information not related to patient care, then usually</p> <p>5 they are discouraged to put all those irrelevant</p> <p>6 information into a report. So that's the so-called</p> <p>7 pathologist report requirement.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. Would you agree with me that histologic</p> <p>10 evaluation can add insight into the pathophysiology of</p> <p>11 mesh complications?</p> <p>12 A. I think you have different levels. One is a</p> <p>13 clinical service level; the other is for research level.</p> <p>14 If you want to do some research project for those</p> <p>15 relatively new things and are emerging kind of clinical</p> <p>16 significance, then yes, you need to study as many para-</p> <p>17 meters as you can. And then for clinical service, usually</p> <p>18 just brief to the point. As soon as you have clinical</p> <p>19 impact, then you put on. If you miss those clinical</p> <p>20 impact, then the clinician even will come back to ask</p> <p>21 you: So, hey, did you see that or that? Mainly because</p> <p>22 those points are important for clinical decision.</p> <p>23 Q. So am I understanding you correctly that</p> <p>24 unless -- let's go to mesh specifically.</p> <p>25 A. Sure.</p>

<p style="text-align: right;">Page 62</p> <p>1 Q. Unless you find something that's going to</p> <p>2 impact the patient's care and treatment, there's no</p> <p>3 reason to document it?</p> <p>4 A. Right. From pathology report perspective.</p> <p>5 Q. So that might explain why a significant number</p> <p>6 of meshes have gross examination only or, in fact,</p> <p>7 sometimes are tossed in the trash without examination at</p> <p>8 all? Would you agree?</p> <p>9 MR. SNELL: Form.</p> <p>10 Go ahead.</p> <p>11 A. Yes. If the gross specimen does not look very</p> <p>12 significant, then clinically no indication for whatever</p> <p>13 the purpose is is recorded in the requisition sheet.</p> <p>14 Yes, based on routine pathology practice, many explanted</p> <p>15 material can be just a gross only. That's part of the</p> <p>16 routine process, that's true.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. What is polypropylene?</p> <p>19 A. Polypropylene is the chemical substance for</p> <p>20 the mesh, right?</p> <p>21 Q. Is it a plastic?</p> <p>22 A. It's a plastic, I suppose, yes.</p> <p>23 Q. You are not putting yourself up as a material</p> <p>24 expert; is that correct?</p> <p>25 A. Correct. I'm not a material expert.</p>	<p style="text-align: right;">Page 64</p> <p>1 should be reported, then we have our professional kind of</p> <p>2 criteria. We put down based like residents, based on</p> <p>3 their trainings, and attendings based on their</p> <p>4 professions or subspecialties. And we will put all these</p> <p>5 relevant information for clinical purpose.</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. And just to make sure I have that clear, it's</p> <p>8 yes, it doesn't matter, correct?</p> <p>9 MR. SNELL: Form. Misstates.</p> <p>10 MS. THOMPSON: Could you read back his</p> <p>11 answer to the last question, just the first sentence.</p> <p>12 (Record read by the Court Reporter.)</p> <p>13 MS. THOMPSON: Okay.</p> <p>14 MR. SNELL: And there was an objection in</p> <p>15 there, correct?</p> <p>16 THE COURT REPORTER: Yes.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. What other medical devices do you examine as</p> <p>19 part of your job as a GYN pathologist?</p> <p>20 A. I think overall is the repair of mesh-related</p> <p>21 things. When I was a resident in overall general</p> <p>22 surgical pathology practice, then I have examined many</p> <p>23 other medical devices, such as some kind for bone broken,</p> <p>24 fractures, fixations, or cardiac kind of devices, stents,</p> <p>25 many things.</p>
<p style="text-align: right;">Page 63</p> <p>1 Q. And you're not an engineer, correct?</p> <p>2 A. I'm not engineer expert.</p> <p>3 Q. And you're not a medical device expert,</p> <p>4 correct?</p> <p>5 MR. SNELL: Form.</p> <p>6 A. I'm not a medical device expert, but I usually</p> <p>7 evaluate the tissue response to the medical device when</p> <p>8 they get explanted.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. But only if you feel that the tissue response</p> <p>11 is going to impact a patient's treatment, correct?</p> <p>12 A. Yes. Usually when we see those specimens in</p> <p>13 either gross or microscopic findings are related to or</p> <p>14 has clinical significance, then we are going to put them</p> <p>15 in the report.</p> <p>16 Q. Because, in your opinion, if it's not, then</p> <p>17 the tissue response doesn't matter, correct?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. What shall I say? This is kind of usually</p> <p>20 yes. If we -- within our specialty, when we practice</p> <p>21 pathology, yes, we focus on the clinical service,</p> <p>22 basically. If just for documentation purpose, then</p> <p>23 that's also part of the clinical service. Yeah, we need</p> <p>24 to document that.</p> <p>25 But whether -- which microscopic finding</p>	<p style="text-align: right;">Page 65</p> <p>1 But within the GYN pathology field, yes,</p> <p>2 we do -- usually do not have many, you know, implants</p> <p>3 there, except this repair mesh or sling or for prolapse.</p> <p>4 Q. So you would agree with me, then, that mesh is</p> <p>5 the only permanently implanted foreign material placed in</p> <p>6 the pelvic region?</p> <p>7 MR. SNELL: Form.</p> <p>8 A. Yeah, for women.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. For women, yes. Thanks for clarifying that.</p> <p>11 Let's go to your report, Dr. Zheng --</p> <p>12 A. Sure.</p> <p>13 Q. -- please.</p> <p>14 Why did you include a definition of</p> <p>15 biocompatibility in your report?</p> <p>16 A. I think biocompatibility issue is related to</p> <p>17 my examinations, because these -- when you have some</p> <p>18 implants or medical device, a foreign body get into the</p> <p>19 tissues. Then one of the common situation is whether the</p> <p>20 medical device can stay there for certain period. That's</p> <p>21 related to the biocompatibility, so one of the common</p> <p>22 situations. So that's why I think it serves as a</p> <p>23 foundation for my future statement. That's the reason I</p> <p>24 put it in there.</p> <p>25 MS. THOMPSON: Have we marked his report?</p>

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<p>1 I don't believe so.</p> <p>2 Let's go ahead and mark your report. I'm</p> <p>3 marking your expert report as Exhibit 4, Dr. Zheng.</p> <p>4 THE WITNESS: Sure. I have that. Thank</p> <p>5 you.</p> <p>6 (Marked for Identification:</p> <p>7 Deposition Exhibit No. 4)</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. Could you read me, at the bottom of page 2,</p> <p>10 the definition of biocompatibility that you include in</p> <p>11 your report?</p> <p>12 A. Page 2.</p> <p>13 Q. The last sentence.</p> <p>14 A. Okay. The biocompatibility of long-term</p> <p>15 implantable medical devices is the ability of the device</p> <p>16 to perform its intended function, with the desired degree</p> <p>17 of incorporation in the host, without eliciting much</p> <p>18 undesirable local or systemic effects in the host.</p> <p>19 Q. And it appears that you took that definition</p> <p>20 from -- just looking back at your citation list, from an</p> <p>21 article by Williams?</p> <p>22 A. Yes.</p> <p>23 Q. Titled, On the Mechanisms of Biocompatibility;</p> <p>24 is that correct?</p> <p>25 A. Correct.</p>	<p>1 Q. And you would agree with me, Dr. Zheng, that</p> <p>2 the word eliciting much desirable -- undesirable and</p> <p>3 eliciting any undesirable local or systemic effects</p> <p>4 differ in their meaning in the context of this sentence,</p> <p>5 right?</p> <p>6 MR. SNELL: Form.</p> <p>7 MS. THOMPSON: I can phrase it again.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. You replaced Dr. Williams' word "any" with the</p> <p>10 word "much," correct?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. Correct.</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. If you would look at page -- the page just</p> <p>15 before that, 2950, in the same article, the authoritative</p> <p>16 article by Dr. Williams.</p> <p>17 A. 2950?</p> <p>18 Q. Yeah. One page earlier.</p> <p>19 A. Okay.</p> <p>20 Q. Would you start with the last sentence on that</p> <p>21 page, It is clear, and read that as well?</p> <p>22 A. Which one? You mean under 8?</p> <p>23 Q. Yes.</p> <p>24 A. The whole paragraph or --</p> <p>25 Q. Just the last sentence, beginning, It is</p>
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<p>1 Q. And I would assume that you considered this</p> <p>2 article authoritative on biocompatibility since you used</p> <p>3 it in your report, correct?</p> <p>4 A. I think so from that point of view.</p> <p>5 MS. THOMPSON: I'm going to mark the</p> <p>6 Williams article as Exhibit 5.</p> <p>7 THE WITNESS: Thank you.</p> <p>8 (Marked for Identification:</p> <p>9 Deposition Exhibit No. 5)</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Would you turn to the last page of that</p> <p>12 article. And I believe this is where your definition in</p> <p>13 your report came from, the italicized paragraph just</p> <p>14 before number 9, Conclusions, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And would you read that to me, please, the</p> <p>17 definition from the Williams article?</p> <p>18 A. Biocompatibility refers to the ability of a</p> <p>19 biomaterial to perform its desired function with respect</p> <p>20 to a medical therapy, without eliciting any undesirable</p> <p>21 local or systemic effects at a recipient or beneficiary</p> <p>22 of that therapy, but generating the most appropriate</p> <p>23 beneficial cellular or tissue response in that specific</p> <p>24 situation, and optimizing the clinical relevant</p> <p>25 performance of that therapy.</p>	<p>1 clear.</p> <p>2 A. It is clear from some well established</p> <p>3 situations, in which there is ample clinical evidence,</p> <p>4 that the principal component of the material's</p> <p>5 biocompatibility is that, whatever the desired function,</p> <p>6 the material shall do no harm, just as the first</p> <p>7 principle of Hippocrates was that the doctor should do no</p> <p>8 harm.</p> <p>9 Q. And would you agree with that statement?</p> <p>10 A. Sure.</p> <p>11 Q. As a GYN pathologist and an at least trained</p> <p>12 OB-GYN doctor, would you agree with me that the vagina is</p> <p>13 a unique organ or environment as far as the body goes?</p> <p>14 A. Yes. It has uniqueness compared to the body,</p> <p>15 other parts of the body.</p> <p>16 Q. And describe for me every way that you would</p> <p>17 consider the vagina unique. That's professionally</p> <p>18 speaking.</p> <p>19 A. Okay. It's a reproductive organ. All right.</p> <p>20 And physiologically, you know, serves the function mainly</p> <p>21 for reproductive function. Okay? And then in modern</p> <p>22 society, sure, sexual activity is one of the main</p> <p>23 function occur within the vagina. So that's, I think,</p> <p>24 one of the main uniqueness.</p> <p>25 Then since the vagina is connecting or</p>

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<p>1 immediate adjacent to the urethra structure, then it's</p> <p>2 related to then urination or other functions. Okay.</p> <p>3 I think what else you want to know? We</p> <p>4 can keep going for a chapter like that.</p> <p>5 Q. We can go a little while longer. I'll cut you</p> <p>6 off if we get to lunch break.</p> <p>7 A. And then it also connects to the cervix and</p> <p>8 then from cervix to the uterus. Then that's forming the</p> <p>9 internal reproductive tract of the female reproductive</p> <p>10 system.</p> <p>11 Then outgoing, it connects to the opening</p> <p>12 to the vulva area. Then we have labia minora as well as</p> <p>13 labia majora, those anatomical structures. So that</p> <p>14 basically saying that the vagina conditions is</p> <p>15 nonsterile, because it's open to the outside world. All</p> <p>16 right?</p> <p>17 Q. So, so far we have, in our list of unique</p> <p>18 properties of the vagina, we have the reproductive and</p> <p>19 sexual function?</p> <p>20 A. Uh-huh.</p> <p>21 Q. We have that it's immediately adjacent to the</p> <p>22 urethra?</p> <p>23 A. Yes.</p> <p>24 Q. And you would agree immediately adjacent to</p> <p>25 the bladder as well?</p>	<p>1 as vaginal wall.</p> <p>2 Q. And then the bladder wall consists of what?</p> <p>3 A. Bladder wall has a bladder mucosa, which is</p> <p>4 transitional cell type of transitional cells on the top,</p> <p>5 then we also have submucosa connective tissue, then has</p> <p>6 muscular wall.</p> <p>7 Q. And that muscle is smooth muscle, correct?</p> <p>8 A. Both of them they are smooth muscle.</p> <p>9 Q. And that description of the bladder was from</p> <p>10 the inside of the bladder out, correct, starting with the</p> <p>11 mucosa?</p> <p>12 A. Starting from mucosa, submucosa, then muscular</p> <p>13 layers.</p> <p>14 Q. And am I correct that the vaginal wall thins</p> <p>15 with menopause?</p> <p>16 A. Yes. Because estrogen plays a big role there.</p> <p>17 Q. And would you approximate the distance between</p> <p>18 the vaginal wall and the bowel, the rectum, to be</p> <p>19 approximately one centimeter, also?</p> <p>20 A. It's maybe little bit more, because -- yes,</p> <p>21 it's about similar situation. But it's just immediate,</p> <p>22 because it's not like everything stick so tightly. Some</p> <p>23 area is closer; some area is a little bit more space.</p> <p>24 Q. So we have the immediately adjacent to other</p> <p>25 organs. And I think another unique feature that you just</p>
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<p>1 A. Yes. Because the female urethra is relatively</p> <p>2 short; therefore, the adjacent organ is the bladder.</p> <p>3 Q. And you would agree with me that it's also</p> <p>4 immediately adjacent posteriorly to the rectum and anus,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. By immediately adjacent, can you tell me</p> <p>8 how -- what the distance is between -- the average</p> <p>9 distance between the vaginal wall and the bladder wall?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. In average, it's probably less than a</p> <p>12 centimeter, because in those wall -- if you counting the</p> <p>13 loose connective tissue, then sometimes is over a</p> <p>14 centimeter.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. So the area -- well, am I correct that the</p> <p>17 skin of the vagina is usually called the mucosa, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And is it correct that there's a muscular</p> <p>20 layer under that that's usually called the submucosa?</p> <p>21 A. No. Submucosa area is usually the loose</p> <p>22 connective tissue. Then underneath of these loose</p> <p>23 connective tissue, there is a muscular wall.</p> <p>24 Q. Okay.</p> <p>25 A. Then put them all together, then we can call</p>	<p>1 mentioned was that the thickness of the wall can change</p> <p>2 with age and probably other conditions as well, correct?</p> <p>3 A. Correct.</p> <p>4 MR. SNELL: Form.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. Would you agree with me that the vagina is</p> <p>7 densely innervated?</p> <p>8 A. Vagina, yes, has -- in average, has more nerve</p> <p>9 innervation or nerve fibers compared to like rectum or</p> <p>10 the bladder.</p> <p>11 Q. How about compared to the anterior abdominal</p> <p>12 wall?</p> <p>13 A. Also should have more.</p> <p>14 Q. Would it surprise you if that was</p> <p>15 approximately 11 times more nerves in the vagina than in</p> <p>16 the anterior abdominal wall?</p> <p>17 MR. SNELL: Foundation.</p> <p>18 A. Frankly speaking, I'm not aware of the number,</p> <p>19 how many times they have.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. But it is --</p> <p>22 A. But it is more. That's the general situation.</p> <p>23 Q. All right. And would you also agree that it's</p> <p>24 densely vascularized?</p> <p>25 A. Yes. There's lots of vessels there. Lots of</p>

<p style="text-align: right;">Page 74</p> <p>1 vessels, yes.</p> <p>2 Q. And that would include more vascularized than</p> <p>3 the anterior abdominal wall?</p> <p>4 A. In general, yes.</p> <p>5 Q. And I won't even try to give you a number</p> <p>6 there, so...</p> <p>7 Would you also agree with me that the</p> <p>8 vagina is a dynamic organ?</p> <p>9 A. Correct. Because it can be like in the</p> <p>10 infancy conditions compared to reproductive age and</p> <p>11 compared to postmenopausal woman, yes, they are dynamic,</p> <p>12 they can change.</p> <p>13 Q. And by dynamic, I think we mean the same</p> <p>14 thing, that it needs to remain flexible and pliable to</p> <p>15 accommodate different conditions in the pelvis, correct?</p> <p>16 A. Correct.</p> <p>17 Q. So at least in the -- when we're talking</p> <p>18 vagina, stiffness is not a good thing for the vagina,</p> <p>19 correct?</p> <p>20 A. You need elasticity.</p> <p>21 Q. And that would be -- I think that was probably</p> <p>22 about three or four more unique features of the vagina</p> <p>23 that I won't go through them all again, correct?</p> <p>24 A. Sure.</p> <p>25 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 76</p> <p>1 that. I didn't ask your experts about what you-all</p> <p>2 talked about.</p> <p>3 MS. THOMPSON: You're right.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. Did the lawyers show you any documents as far</p> <p>6 as clinical trials performed on TVT-O prior to marketing?</p> <p>7 A. I'm not aware of that. But based on my</p> <p>8 reading, seems there are multiple publications regarding</p> <p>9 the TVT-O situation compared to the conventional method</p> <p>10 for repair for stress urinary incontinence treatment.</p> <p>11 Q. Are you aware of any of those publications</p> <p>12 that came out prior to marketing the TVT-O device?</p> <p>13 A. I'm not aware, you know, prior to those</p> <p>14 publications.</p> <p>15 Q. And you said that biocompatibility was</p> <p>16 important for a medical device placed in a certain area</p> <p>17 of the body, and a clinical trial is important as well,</p> <p>18 correct?</p> <p>19 A. But, in general, any medical device, if you</p> <p>20 want to put into a patient body as a clinical service or</p> <p>21 clinical treatment, you have to have those tests done.</p> <p>22 Nobody can just use -- create something and without these</p> <p>23 validation process, then, you know, just provide to</p> <p>24 patient.</p> <p>25 Q. Okay. Dr. Zheng, if you would turn to your</p>
<p style="text-align: right;">Page 75</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Would you agree with me that, to be</p> <p>3 biocompatible, a material or device needs to perform in</p> <p>4 the actual area where it is to be placed?</p> <p>5 A. Yes.</p> <p>6 Q. So, in other words, if you have a device that</p> <p>7 works in one part of the body but you're putting it in</p> <p>8 another part of the body, you need to make sure that it's</p> <p>9 also going to be biocompatible with the new part of the</p> <p>10 body, correct?</p> <p>11 A. Not only biocompatible. You may also have to</p> <p>12 do a test, a so-called clinical trial, and to make sure</p> <p>13 they actually work in the majority of the situation to</p> <p>14 satisfy the clinical purposes.</p> <p>15 Q. Do you know if there was a clinical trial done</p> <p>16 on the TVT-O device before it was marketed?</p> <p>17 A. For this particular question, I'm not sure.</p> <p>18 Q. So the lawyers for Ethicon never discussed</p> <p>19 with you any clinical studies or trials done on TVT-O</p> <p>20 before placing it on the market?</p> <p>21 MR. SNELL: Form.</p> <p>22 Actually he's not going to discuss the</p> <p>23 particulars of our discussions --</p> <p>24 MS. THOMPSON: Fair enough.</p> <p>25 MR. SNELL: -- if your question goes to</p>	<p style="text-align: right;">Page 77</p> <p>1 report, the next sentence after the one we read a little</p> <p>2 while ago on the bottom of page 2. That states, A small</p> <p>3 amount of inflammation near the interface between the</p> <p>4 foreign body and the tissue is related to better</p> <p>5 biocompatibility. What is your basis for this opinion?</p> <p>6 A. That basically is common knowledge within the</p> <p>7 medical field. If you don't have a biocompatible</p> <p>8 material planted into human body, then will elicit very</p> <p>9 strong human tissue reactions.</p> <p>10 If you have a minor or mild chronic</p> <p>11 inflammation, then usually indicating overall tissue</p> <p>12 reaction to particular medical device is acceptable.</p> <p>13 Q. So you're saying that a small amount of</p> <p>14 inflammation is better than a large amount of</p> <p>15 inflammation, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Not a small amount of inflammation is better</p> <p>18 than no inflammation?</p> <p>19 A. No inflammation, yes, it certainly is better.</p> <p>20 Q. Okay. And when you're talking about the small</p> <p>21 amount of inflammation that is related to better</p> <p>22 biocompatibility, what type of inflammation are you</p> <p>23 referring to?</p> <p>24 A. Classically, when we examine those medical</p> <p>25 devices for particularly for those slings, then they</p>

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<p>1 remove them usually is after a certain period of the</p> <p>2 implantation. Therefore, majority of such material</p> <p>3 contains chronic inflammation rather than acute</p> <p>4 inflammation, except for infections or other conditions</p> <p>5 happen.</p> <p>6 Q. And you've seen the same chronic inflammation</p> <p>7 regardless of how long it's been implanted, correct?</p> <p>8 A. Depending on the degree. Individual case or</p> <p>9 individual specimens have individual situations. More or</p> <p>10 less, they have certain degree of chronic inflammation.</p> <p>11 Q. And you're not suggesting that chronic</p> <p>12 inflammation that goes on indefinitely is better than not</p> <p>13 having the chronic inflammation, correct?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. As I said, no inflammation certainly will be</p> <p>16 better than with inflammation.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. All right. Going to the foreign body response</p> <p>19 paragraph, what is the difference between a response to</p> <p>20 surgery -- the healing response to surgery with and</p> <p>21 without a foreign --</p> <p>22 A. Foreign body?</p> <p>23 Q. -- body? Please.</p> <p>24 A. In general, surgical procedure will cause</p> <p>25 tissue damage. That's for sure, because the knife cuts</p>	<p>1 been that the foreign body has been implanted?</p> <p>2 MR. SNELL: Form.</p> <p>3 Go ahead.</p> <p>4 A. In general. In general, that's a correct</p> <p>5 statement.</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. Is pore size important when you're talking</p> <p>8 about the body's response to plastic mesh?</p> <p>9 A. Pore size is one of the important factors</p> <p>10 related to the biocompatibility or tissue integration. I</p> <p>11 think we -- I have discussed some area. Particularly we</p> <p>12 discussed a lot in the Lewis case. But yes, the answer</p> <p>13 is yes.</p> <p>14 Q. And when you're talking about tissue</p> <p>15 integration, the desired tissue integration is the same</p> <p>16 tissue that's surrounding the mesh, correct?</p> <p>17 A. Getting into the pore and then surrounding the</p> <p>18 pore.</p> <p>19 Q. Into the pore and surrounding the pore?</p> <p>20 A. Surrounding the mesh, yes.</p> <p>21 Q. And in the area that the TVT-O is implanted,</p> <p>22 that surrounding tissue is loose connective tissue as</p> <p>23 you've described, correct?</p> <p>24 A. Majority of them they are connective tissue,</p> <p>25 that's right.</p>
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<p>1 the skin, for instance, make a cut, then separate the</p> <p>2 tissue already. Then with or without foreign body makes</p> <p>3 a difference, because if without foreign body or medical</p> <p>4 device implant, then the tissue just react to the injury.</p> <p>5 Then with foreign body device or medical</p> <p>6 device get into the tissue, then not only the body or the</p> <p>7 tissue will react to the tissue damage and also will</p> <p>8 react to the foreign material implanted in that area. So</p> <p>9 that's the main difference.</p> <p>10 Q. So with surgery without using a foreign body,</p> <p>11 the inflammatory response is self-limited, correct?</p> <p>12 MR. SNELL: Form.</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. In the normal healing process?</p> <p>15 A. Correct.</p> <p>16 Q. And with a foreign body, and with mesh</p> <p>17 specifically, the inflammatory process continues</p> <p>18 indefinitely, correct?</p> <p>19 A. Basically indefinitely, but to a certain</p> <p>20 degree, tissue will adapt that kind of environment, then</p> <p>21 weaned tissue response reaction rate. That means in</p> <p>22 certain situations or in majority of the situations, the</p> <p>23 tissue response wean out. That means getting reduced.</p> <p>24 Q. But you would agree that there is a continued</p> <p>25 chronic inflammatory response regardless of how long it's</p>	<p>1 Q. Loose connective tissue?</p> <p>2 A. Right. Or some of them can have little bit</p> <p>3 more dense.</p> <p>4 Q. No. We're talking about what the normal</p> <p>5 tissue is in the vagina --</p> <p>6 A. Right.</p> <p>7 Q. -- is loose connective tissue, correct?</p> <p>8 A. Right. Or we should say just connective</p> <p>9 tissue, because it's very difficult to define what is</p> <p>10 so-called loose, what is so-called dense. So overall</p> <p>11 it's connective tissue will be a better concept to cover.</p> <p>12 Q. I think you said loose before. So what is</p> <p>13 your definition of loose connective tissue?</p> <p>14 A. Loose connective tissue basically you have</p> <p>15 less cellular density or less amount of fibroblasts</p> <p>16 compared to dense connective tissue.</p> <p>17 Q. And what does dense connective tissue consist</p> <p>18 of?</p> <p>19 A. Dense connective tissue, that means all of</p> <p>20 them under microscope you see the fibroblasts and</p> <p>21 collagen bundles.</p> <p>22 Q. And would dense connective tissue be used</p> <p>23 synonymously with fibrous connective tissue?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. No. Fibrous -- fibrous connective tissue is</p>

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<p>1 also a general concept or terminology to describe all</p> <p>2 kinds of fibrotic component as well as fibroblasts and</p> <p>3 then vessels. Even occasionally you have some nerve</p> <p>4 fibers there and some inflammatory cells.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. Do you see loose connective tissue in the</p> <p>7 pores of transvaginally-placed explanted mesh?</p> <p>8 A. From those majority of situations, we see</p> <p>9 more, in general, connective tissue, rather than try to</p> <p>10 divide them into either loose or dense.</p> <p>11 Q. But even though the normal connective tissue</p> <p>12 is loose connective tissue, you don't generally see that</p> <p>13 in the pores of the mesh, correct?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. In general, within the incorporated tissue</p> <p>16 into the mesh pores, we see less loose connective tissue.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. And when we look at slides a little bit later</p> <p>19 on, I'm going to have you show me where you see the loose</p> <p>20 connective tissue.</p> <p>21 A. Sure.</p> <p>22 Q. And the pore is the same thing as a hole,</p> <p>23 right?</p> <p>24 A. Correct.</p> <p>25 Q. And have you ever actually measured the pore</p>	<p>1 A. Somewhere maybe. Lightweight versus</p> <p>2 heavyweight.</p> <p>3 Q. And so your opinion is that lightweight</p> <p>4 is better than heavyweight, correct?</p> <p>5 MR. SNELL: Form.</p> <p>6 A. As I said, I'm not the material expert. But</p> <p>7 overall I think, based on my evaluation, pathological</p> <p>8 evaluation from those meshes, I'm not able to tell this</p> <p>9 mesh is lightweight versus heavyweight.</p> <p>10 But based on literature, it seems</p> <p>11 lightweight should be better.</p> <p>12 (By Ms. Thompson)</p> <p>13 Q. And you would agree that Prolene in the</p> <p>14 literature is usually listed as a heavyweight mesh?</p> <p>15 MR. SNELL: Form.</p> <p>16 A. Can you lead me which section I was -- I have</p> <p>17 written regarding this paragraph?</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. That's what I was looking for myself, so it</p> <p>20 escaped both of us, but I'll find it.</p> <p>21 MR. SNELL: I'm going to object. This is</p> <p>22 outside the scope of his opinion.</p> <p>23 MS. THOMPSON: It's in his report.</p> <p>24 MR. SNELL: I don't think he opines on</p> <p>25 which is better as opposed to just the basic --</p>
Page 83	Page 85
<p>1 size of TVT mesh?</p> <p>2 A. I measure -- typically under microscope, I can</p> <p>3 estimate, I should say, rather than truly measure. I</p> <p>4 can't give like one micron versus two micron away. I</p> <p>5 usually give a rough estimation.</p> <p>6 Q. And that's done how?</p> <p>7 A. Mainly we use so-called internal references.</p> <p>8 Internal reference that means based on cell size.</p> <p>9 Certain cells has certain cell size. It's well</p> <p>10 documented in the medical literature.</p> <p>11 So, for instance, if we have inflammatory</p> <p>12 cell like lymphocyte, it's about 10 to maybe 15 micron</p> <p>13 size. Then if we use this size and we have multiple</p> <p>14 lymphocytes there, then we add them together and estimate</p> <p>15 how many microns. So that's the way.</p> <p>16 Q. And you've never measured the pore size in</p> <p>17 vivo, correct?</p> <p>18 A. In vivo, we -- in vivo, what do you mean?</p> <p>19 Within the vagina?</p> <p>20 Q. Right.</p> <p>21 A. Yeah. I'm not a surgeon. I don't see them.</p> <p>22 Usually even, you know, for those cases with mesh</p> <p>23 exposure, people are not able to measure the pore size.</p> <p>24 Q. And I think you mentioned that the weight of</p> <p>25 mesh is important as well, correct?</p>	<p>1 MS. THOMPSON: Well, let's definitely find</p> <p>2 it, then, because I disagree.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. Okay. Dr. Zheng, turn to page 3.</p> <p>5 A. Yes.</p> <p>6 Q. And in the first paragraph on that page, you</p> <p>7 state, The basic factors related to the overall</p> <p>8 biocompatibility of the mesh material are pore size,</p> <p>9 weight, elasticity and filamental structure, correct?</p> <p>10 A. Yes.</p> <p>11 Q. So weight we just discussed, and you said that</p> <p>12 in the literature, at least, lightweight is preferable to</p> <p>13 heavyweight, correct?</p> <p>14 MR. SNELL: Form. Misstates.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. Well, is lightweight -- when you say the --</p> <p>17 A. Frankly speaking, yes. This sentence, these</p> <p>18 basic structures -- the sentence basically is derived</p> <p>19 from certain literatures. But in detail, how to evaluate</p> <p>20 the weight and how to define light versus heavy, I'm not</p> <p>21 sure. Okay? So this is overall situation rather than go</p> <p>22 through details.</p> <p>23 Q. All right. So you would say, then, that --</p> <p>24 you're saying that your opinions that the weight is a</p> <p>25 basic factor related to the overall biocompatibility of</p>

<p style="text-align: right;">Page 86</p> <p>1 the mesh material is what you have determined from the</p> <p>2 literature, correct?</p> <p>3 A. Correct.</p> <p>4 Q. And I think after that I asked you the</p> <p>5 question, did you know that Prolene is usually considered</p> <p>6 a heavyweight mesh in the literature? And is that your</p> <p>7 understanding of the literature?</p> <p>8 MR. SNELL: Form.</p> <p>9 Go ahead.</p> <p>10 A. I'm not sure. This is -- that's why I say</p> <p>11 later on I did not pay attention to how to define heavy</p> <p>12 versus light, because from my practice point of view,</p> <p>13 it's not related to my opinion in terms of tissue</p> <p>14 response to the mesh specimen.</p> <p>15 (Marked for Identification:</p> <p>16 Deposition Exhibit No. 6)</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. All right. Well, I didn't bring a lot of</p> <p>19 literature on that point, but I did bring an article that</p> <p>20 you are using for another purpose that I will mark as</p> <p>21 Exhibit 6, and this is the article by Cobb.</p> <p>22 And if you would just turn to the second</p> <p>23 page where it states the concept of lightweight mesh.</p> <p>24 A. Yes.</p> <p>25 Q. And this article states that several</p>	<p style="text-align: right;">Page 88</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. So you are not really familiar with the hernia</p> <p>3 repair literature regarding polypropylene mesh and the</p> <p>4 complications associated with hernia repair mesh?</p> <p>5 A. Correct.</p> <p>6 Q. What do you mean by the last basic factor</p> <p>7 related to the overall biocompatibility of the mesh</p> <p>8 material, filamental structure?</p> <p>9 A. Filamental structure basically how these, you</p> <p>10 know, filament knit together basically. My understanding</p> <p>11 is that. All right. If the filament, for instance,</p> <p>12 forming sheets without -- with very small pore size, then</p> <p>13 certainly will not allow good tissue integration. That's</p> <p>14 overall filament structure.</p> <p>15 However, if you have certain pore size,</p> <p>16 then knit in certain way, that may help tissue</p> <p>17 integration. That's my understanding for the filament</p> <p>18 structure.</p> <p>19 Q. And that's from the literature as well, not</p> <p>20 personal opinion -- not personal experience?</p> <p>21 A. No. I don't have that particular interest,</p> <p>22 too.</p> <p>23 Q. Biocompatibility refers to the material</p> <p>24 itself; in the case of a TVT-O, the polypropylene plastic</p> <p>25 material, correct?</p>
<p style="text-align: right;">Page 87</p> <p>1 comparable formulations of heavyweight polypropylene are</p> <p>2 available with a similar polypropylene content as Marlex</p> <p>3 including Prolene. Is that what this article says?</p> <p>4 A. This article says it that way.</p> <p>5 Q. Okay. And the next basic factor related to</p> <p>6 the overall biocompatibility of a mesh material is</p> <p>7 elasticity. Could you explain that to me?</p> <p>8 A. Elasticity basically, based on my</p> <p>9 understanding, is you -- it's not like -- for instance,</p> <p>10 this iron or steel material, then the elasticity will be</p> <p>11 a lot less than plastic. Then you need a certain degree</p> <p>12 to tolerate the stretch. Therefore, that represent</p> <p>13 elasticity.</p> <p>14 Q. And that's important because of what we</p> <p>15 already discussed --</p> <p>16 A. Right.</p> <p>17 Q. -- of the vagina?</p> <p>18 A. Because -- yeah. The particular organ site,</p> <p>19 to serve the function you need elasticity.</p> <p>20 Q. And are you aware of studies showing stiffness</p> <p>21 of polypropylene mesh associated with abdominal wall</p> <p>22 repairs?</p> <p>23 MR. SNELL: Form.</p> <p>24 A. I'm not aware of that, because I rarely read</p> <p>25 the literature for the, you know, hernia repair.</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Yeah. Overall reflects the material -- the</p> <p>2 relationship between the material and the tissue</p> <p>3 response.</p> <p>4 Q. And the tissue that it's in, right?</p> <p>5 You would agree with me, though, that the</p> <p>6 TVT-O kit sold by Ethicon is more than just the material,</p> <p>7 wouldn't you?</p> <p>8 MR. SNELL: Form.</p> <p>9 A. I don't understand the question.</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Well, I think what I mean -- it probably</p> <p>12 wasn't a very good question -- the kit contains surgical</p> <p>13 instruments --</p> <p>14 A. Yes.</p> <p>15 Q. -- needles, et cetera. And the method in</p> <p>16 which it's placed is dictated by the combination of the</p> <p>17 material as well as the instruments to insert?</p> <p>18 A. Sure.</p> <p>19 Q. Does that help you understand the question?</p> <p>20 A. Sure. Yes.</p> <p>21 Q. So the question then is, the kit is more than</p> <p>22 just the plastic material of the tape, correct?</p> <p>23 A. Yes. The kit contains all kinds of condition</p> <p>24 or material to help this procedure.</p> <p>25 Q. In your opinion, is polypropylene biologically</p>

<p style="text-align: right;">Page 90</p> <p>1 inert?</p> <p>2 A. Yes.</p> <p>3 Q. In your opinion, is polypropylene chemically</p> <p>4 inert?</p> <p>5 A. I'm not sure, because I'm not -- I did not</p> <p>6 study this, and also I'm not expert for the material.</p> <p>7 Q. Okay. So biologically inert, yes. What does</p> <p>8 that mean to you?</p> <p>9 A. That means it has -- overall has a good</p> <p>10 biocompatibility. It can stay within the tissue for</p> <p>11 longer time, for long time.</p> <p>12 Q. And --</p> <p>13 A. And then the tissue response is within the</p> <p>14 acceptable range and still maintains the overall</p> <p>15 biological function.</p> <p>16 Q. And does that mean that it does not degrade</p> <p>17 over time?</p> <p>18 A. My overall understanding is the mesh is</p> <p>19 considered as a nondegradable material.</p> <p>20 Q. Can you explain -- or explain to me how a</p> <p>21 TVT-O mesh is put into the body.</p> <p>22 A. First of all, I'm not a surgeon, so the</p> <p>23 overall, the detail procedure, I do not perform.</p> <p>24 Therefore, I don't have the detail to tell you.</p> <p>25 But the overall situation is from the</p>	<p style="text-align: right;">Page 92</p> <p>1 Vague as to who. He's not testifying important as to a</p> <p>2 surgeon. He can only testify what is important to him as</p> <p>3 a pathologist. That's the basis of my objection.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. Take out the word important. What are the</p> <p>6 structures in the obturator foramen?</p> <p>7 A. I think within that structure, you have</p> <p>8 vessels, you have muscles --</p> <p>9 Q. What vessels?</p> <p>10 A. What kind of special vessels? You know, I'm</p> <p>11 not sure there is a special name within those, because if</p> <p>12 you need to anatomically specially identify vessel,</p> <p>13 usually it's quite big. And small ones just to supply</p> <p>14 the nutrition to those adjacent tissues.</p> <p>15 Q. So we'll go with obturator vessels. How's</p> <p>16 that?</p> <p>17 A. That's fine.</p> <p>18 Q. Okay. So what else?</p> <p>19 A. Then you have muscles, obturator internus,</p> <p>20 obturator externus. And then you may also have some</p> <p>21 peripheral nerve branches or nerve twigs, small nerve</p> <p>22 fibers.</p> <p>23 Q. Well, isn't it true that you actually have the</p> <p>24 obturator nerve, which is a fairly large nerve, correct?</p> <p>25 A. That's a big one, too.</p>
<p style="text-align: right;">Page 91</p> <p>1 skin, then you have a tape, then through the skin</p> <p>2 incision or either inside out or outside in procedures,</p> <p>3 then have to go through obturator foramen.</p> <p>4 THE COURT REPORTER: Obturator what?</p> <p>5 THE WITNESS: Foramen, F-O-R-A-M-A-N.</p> <p>6 THE COURT REPORTER: Thank you.</p> <p>7 A. That's a special anatomical structure. Well,</p> <p>8 you know that.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. Is the TVT-O an inside out or an outside in</p> <p>11 device?</p> <p>12 A. TVT-O, let me see. It looks like inside out,</p> <p>13 I feel. I watched one video and yes.</p> <p>14 Q. I think you testified before you weren't</p> <p>15 qualified to place a TVT-O?</p> <p>16 A. I'm not qualified.</p> <p>17 Q. And you would probably agree that watching</p> <p>18 that video didn't qualify you?</p> <p>19 A. No. Just try to understand this surgical</p> <p>20 procedure, because for me it's a new thing, too.</p> <p>21 Q. Okay. So it goes through the obturator</p> <p>22 foramen. What are the important anatomical structures in</p> <p>23 the obturator foramen?</p> <p>24 A. That's --</p> <p>25 MR. SNELL: I'm going to object to form.</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. Okay. And then as the tape comes through the</p> <p>2 foramen and before it gets to the skin, what structures</p> <p>3 does it pass through?</p> <p>4 A. I'm not sure what the detail structure goes</p> <p>5 through. You have some connective tissue, some mucosal</p> <p>6 tissue.</p> <p>7 Q. Do you have muscle?</p> <p>8 A. The muscles mainly is external versus internal</p> <p>9 obturator.</p> <p>10 Q. What about the hip adductor muscles? That</p> <p>11 would be the adductor brevis?</p> <p>12 A. I'm not sure for that.</p> <p>13 Q. Okay. So you're not sure, then, what muscles</p> <p>14 the TVT-O passes through during insertion?</p> <p>15 A. I'm pretty sure the pass is through the</p> <p>16 obturator foramen. Therefore, obturator internus,</p> <p>17 obturator externus being passed.</p> <p>18 Q. But beyond the obturator internus and</p> <p>19 externus, you don't know?</p> <p>20 A. I don't know that.</p> <p>21 Q. Okay. You talked about the requisitions that</p> <p>22 you get with mesh specimens, prolapse mesh and sling</p> <p>23 mesh. Do you see different complications listed for</p> <p>24 retropubic slings than you do for transobturator slings?</p> <p>25 A. One of the more common complications probably</p>

<p style="text-align: right;">Page 94</p> <p>1 is bladder perforation, so for TVT-O is more common for 2 bladder perforation. 3 Q. TVT-O is more common to have bladder 4 perforations? 5 A. Based on my impression, yes. 6 Q. But you wouldn't receive, typically, a 7 specimen for a bladder perforation, would you? 8 A. No. Bladder perforation is only clinical 9 record. Usually they don't remove any specimen or any 10 part of the bladder for that. 11 Q. And what other complications are more common 12 with a retropubic sling than a transobturator sling? 13 A. Compare -- they are both procedures. My 14 overall impression is they are comparable. It's not like 15 specifically one way versus the other is more or less. 16 Q. And you're saying comparable in what way? 17 A. I mean like overall cure rate and the overall 18 complication rates. Maybe have some, you know, 19 variations for that, but it's not like dramatically 20 different. 21 Q. So you're saying that the complication rates 22 are the same. But are the complications themselves the 23 same? 24 MR. SNELL: Form. I think that misstates 25 what he said.</p>	<p style="text-align: right;">Page 96</p> <p>1 A. Correct. 2 Q. Do you believe that some patients are 3 predisposed to exaggerated immune and inflammatory 4 responses? 5 A. Some patients, yes. 6 Q. How do you identify those patients? 7 A. From clinical perspective, typically doctors, 8 before doing any of these implantation, will ask any 9 history of like hypersensitive history to certain things 10 or any history of foreign body implantations. Then to 11 see -- to evaluate the overall response or potential 12 response or any hazard or risk for the implantation 13 procedure. 14 Q. Anything else? 15 A. I think that's -- from my understanding, 16 that's the main thing. 17 Q. So doctors should know that or should be 18 informed that there are certain patients that may have a 19 hypersensitivity or an exaggerated immune inflammatory 20 response to polypropylene? 21 MR. SNELL: Form. 22 This is outside the scope of his report. 23 He's not offering an opinion on warnings or what should 24 be told to doctors. He's not testifying in the place of a 25 surgeon. So this isn't within his report or his opinions.</p>
<p style="text-align: right;">Page 95</p> <p>1 A. I think I'm not in particular to answer those 2 questions, mainly because they are all clinical 3 questions. 4 (By Ms. Thompson) 5 Q. But isn't it important for you to have the 6 clinical information when you're determining what might 7 be the cause for the clinical symptom? 8 A. No. For pathologist, we don't need those, 9 which one has more complications related to certain 10 particular situation. We will provide tissue response 11 or the particular findings to the clinicians to help 12 them to future management. 13 Q. So you're saying it's not important to you as 14 a pathologist to know the different types of 15 complications that are associated with different types of 16 meshes? 17 A. Correct. 18 Q. Do you agree that women react differently to a 19 foreign body such as mesh? 20 MR. SNELL: Object to form. 21 A. I agree individual person has individual 22 response. 23 (By Ms. Thompson) 24 Q. And this would include the scope and severity 25 of the body's reaction to the plastic material, correct?</p>	<p style="text-align: right;">Page 97</p> <p>1 MS. THOMPSON: I wasn't asking him as a 2 surgeon. He has in his report the factors that can cause 3 a patient to have an exaggerated or hypersensitive 4 response. So I'm just trying to tease that out, how a 5 doctor determines that. 6 MR. SNELL: I don't see in his report 7 where he has the factors for a hypersensitive response, 8 nor is he speaking on that or designated on that. 9 MS. THOMPSON: Well, he just spoke on it, 10 so -- all right. 11 (By Ms. Thompson) 12 Q. And you also noted several factors for the 13 same exaggerated immune and inflammatory response. And 14 we're reading -- I'm actually reading in your report on 15 page 3. 16 A. Yes. 17 Q. That include the host genetics and the host 18 other physical conditions, smoking, diabetes, et cetera? 19 A. Yes, I agree. 20 Q. It's your opinion that those will impact the 21 host response? 22 A. Correct. For instance, diabetic patient may 23 have higher risk for infection. Therefore, if this kind 24 of patient receive some implants, compared to those 25 patients without diabetes, may pose a higher risk for</p>

<p style="text-align: right;">Page 98</p> <p>1 future infection.</p> <p>2 Q. And so it's very hard to predict who is going</p> <p>3 to have some of these complications and who will not,</p> <p>4 correct?</p> <p>5 A. Correct.</p> <p>6 Q. Describe for me the cascade of the body's</p> <p>7 foreign body response.</p> <p>8 A. Okay. Foreign body response starting from the</p> <p>9 tissue received the foreign material, then at the</p> <p>10 beginning is acute phase, and tissue mainly respond to</p> <p>11 the injury. And then after the acute phase, then --</p> <p>12 usually the acute phase takes about 48 hours. After 48</p> <p>13 hours, then gradually moving to chronic phase.</p> <p>14 Chronic phase, we have different</p> <p>15 inflammatory cellular component compared to acute phase,</p> <p>16 so which typically including lymphocytes, monocytes,</p> <p>17 macrophages, and so on. Okay?</p> <p>18 Then the chronic, these macrophages</p> <p>19 particularly will play a role to try to get rid of the</p> <p>20 foreign material, because the foreign material does not</p> <p>21 belong to the body. So they recognize this is kind of</p> <p>22 hostile material, I don't want them to be there. So they</p> <p>23 will generate a response.</p> <p>24 Then since the medical device typically is</p> <p>25 larger particles compared to those individual cells, so</p>	<p style="text-align: right;">Page 100</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. That the healing process goes to a certain</p> <p>3 point, and then there's no further inflammatory process,</p> <p>4 correct?</p> <p>5 A. So-called healed. After healed, then no</p> <p>6 further reaction.</p> <p>7 Q. So the function of this, these macrophages,</p> <p>8 the body's response, is to eliminate the hostile</p> <p>9 material, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And when the elimination is not possible, the</p> <p>12 body then tries to isolate the hostile material, correct?</p> <p>13 A. That takes long time, yeah. Overall</p> <p>14 situation, yes, try to isolate that. That's a</p> <p>15 reasonable, yes, approach.</p> <p>16 Q. And that's a general description, but that</p> <p>17 applies to mesh as well, would you agree?</p> <p>18 A. Yes. Because mesh is a type of foreign body.</p> <p>19 Q. What is granulation tissue?</p> <p>20 A. Granulation tissue is defined by presence of</p> <p>21 connective tissues as well as vessels and also</p> <p>22 inflammatory cells. That's so-called granulation tissue.</p> <p>23 Q. Is fibrosis the same as scar?</p> <p>24 A. No. Scar is defined by -- typical scar</p> <p>25 defined by pure form of collagen bundles without or with</p>
<p style="text-align: right;">Page 99</p> <p>1 they fuse together to form foreign body giant cells.</p> <p>2 Then these foreign body giant cells serve as a</p> <p>3 synergistic effect to try to get rid of them. That's why</p> <p>4 typically they are surrounding those foreign material,</p> <p>5 for instance, mesh. We see those foreign body giant</p> <p>6 cells all the time under microscope.</p> <p>7 Q. With mesh --</p> <p>8 A. With mesh.</p> <p>9 Q. -- is that correct?</p> <p>10 And you said in your report if the process</p> <p>11 continues -- you're talking about the continuation of the</p> <p>12 inflammatory process beyond acute inflammation, correct?</p> <p>13 MR. SNELL: What page are you on?</p> <p>14 MS. THOMPSON: Page 3. I'm sorry.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. If the process continues, in the next to last</p> <p>17 paragraph. And with mesh, that process is going to</p> <p>18 automatically continue, would you agree?</p> <p>19 A. Yes.</p> <p>20 Q. And with nonmesh surgery -- and I think you</p> <p>21 said this before, so I want to make sure I get it</p> <p>22 correct --</p> <p>23 A. Just --</p> <p>24 MR. SNELL: Let her ask her question.</p> <p>25</p>	<p style="text-align: right;">Page 101</p> <p>1 minimal amount of inactive-looking or dying fibroblasts,</p> <p>2 fibrocells. Okay? That's the definition for scar, a</p> <p>3 pure scar.</p> <p>4 Then fibrosis we have certain degrees,</p> <p>5 typically. We divide them into mild, moderate to severe,</p> <p>6 depending on the microscopic findings. We have different</p> <p>7 degrees.</p> <p>8 Q. You are not saying, are you, that scar</p> <p>9 doesn't -- can't contain blood vessels and nerves, are</p> <p>10 you?</p> <p>11 A. Scar, classic scar, so-called pure scar, does</p> <p>12 not have vessels.</p> <p>13 Q. But it does have nerves or can have nerves,</p> <p>14 correct?</p> <p>15 A. Does not have nerve to scar, but adjacent to</p> <p>16 the scar tissue you can have those vessels and nerves.</p> <p>17 So histologically that means, under microscope, if it is</p> <p>18 scar, we don't see those. It's basically all pure</p> <p>19 collagen bundles.</p> <p>20 Q. So you are telling me today that scar does --</p> <p>21 cannot contain nerves or else you don't call it scar,</p> <p>22 correct?</p> <p>23 A. If you have a nerve, then -- entrapped there</p> <p>24 or something within the scar, that's abnormal finding.</p> <p>25 In normal scar formation, you should not see this.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. So if you do see nerves in scar, it's</p> <p>2 abnormal?</p> <p>3 A. If you consider that's a true scar, then you</p> <p>4 see those, that's abnormal, correct. Or usually that's</p> <p>5 isolated. They are not viable.</p> <p>6 Q. But it doesn't make it not a scar just because</p> <p>7 you see nerves, correct?</p> <p>8 A. Can you repeat that?</p> <p>9 Q. Just because you see nerves within scar, you</p> <p>10 said it was abnormal, but it doesn't disqualify it from</p> <p>11 being called a scar, correct?</p> <p>12 A. No. I think my definition of scar or my</p> <p>13 understanding of a scar overall from the literature, the</p> <p>14 scar is composed by pure collagen bundles without vessel,</p> <p>15 number one. That's why the scar looks whitish.</p> <p>16 Although you have different kind of scars,</p> <p>17 like keloid and other things. That's a different special</p> <p>18 scar. We are not talking too many special situations</p> <p>19 there.</p> <p>20 And then they do not have nerve within the</p> <p>21 scar. That's in the normal situation, because nerve</p> <p>22 cannot grow. Even at the beginning in the process of</p> <p>23 scar formation, you may have some nerve or vessels. Then</p> <p>24 after they mature, these vessels, they vanished. They</p> <p>25 are not functioning anymore.</p>	<p style="text-align: right;">Page 104</p> <p>1 the scar area. Okay? But these findings does not</p> <p>2 disqualify this is a scar, number one.</p> <p>3 Number two, finding such kind of structure</p> <p>4 does not necessarily say these nerves still or nerve</p> <p>5 fibers still maintain the function, because we don't know</p> <p>6 what's the connection to the main nerve.</p> <p>7 (By Ms. Thompson)</p> <p>8 Q. Scars can be painful, correct?</p> <p>9 A. Yes, scars can be painful. That overall</p> <p>10 statement is correct.</p> <p>11 Q. So pain is carried by nerves, pain sensation,</p> <p>12 correct?</p> <p>13 A. It's not necessary. Painful feeling, you</p> <p>14 don't have nerve, also you can feel pain, because pain is</p> <p>15 a feeling. It's a personal feeling. Personal feeling</p> <p>16 can be psychologic.</p> <p>17 Q. Okay. So you're saying that if a patient has</p> <p>18 a scar that is painful, is it more likely than not</p> <p>19 psychologic?</p> <p>20 MR. SNELL: Object to the form. This is</p> <p>21 beyond vague and hypothetical.</p> <p>22 A. We are discussing those very general terms.</p> <p>23 All right. And very general terms can be very loose.</p> <p>24 Therefore, it's not going to be very helpful to help us</p> <p>25 to discuss this particular case. I don't --</p>
<p style="text-align: right;">Page 103</p> <p>1 So, therefore, when you say are you able</p> <p>2 to see reminiscent kind of vascular structure? Yes,</p> <p>3 could be sometimes there, because these area being</p> <p>4 isolated later on because no blood flow get into the</p> <p>5 scar. The original structures just stays there with</p> <p>6 no function. So if you want to see active blood</p> <p>7 vessel-like supplied scar, no, we never see that. All</p> <p>8 right? And, yeah, sometimes you see nerve fibers maybe</p> <p>9 maintained. They're not completely die, but still</p> <p>10 maintained within the structure, but does not necessarily</p> <p>11 say these nerve or nerve-like structure is functioning.</p> <p>12 These are two different concepts.</p> <p>13 Q. So if you see nerves in scar, you said that's</p> <p>14 an abnormal finding. Are you saying that nerves can't be</p> <p>15 normal nerves in scar?</p> <p>16 A. No.</p> <p>17 MR. SNELL: Hold on.</p> <p>18 Objection. Misstates.</p> <p>19 Go ahead.</p> <p>20 A. What I'm saying is if it's a true scar -- for</p> <p>21 instance, we're not talking -- so far not talking about</p> <p>22 mesh. Okay? Like on the skin you have a scar. It's</p> <p>23 very common. On the face you have a scar. Then you take</p> <p>24 a section from the skin area. Then under microscope</p> <p>25 occasionally you may see some kind of nerve fiber within</p>	<p style="text-align: right;">Page 105</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Well, let's just get specific, then, for an</p> <p>3 example.</p> <p>4 A. Yeah.</p> <p>5 Q. Isn't painful scars a serious problem with</p> <p>6 burn victims?</p> <p>7 A. With burn patients?</p> <p>8 Q. Burn patients.</p> <p>9 A. Burn patients may feel pain. That's for sure.</p> <p>10 Whether it's coming from a scar or scar-related</p> <p>11 condition, I'm not sure.</p> <p>12 Q. So you don't know one way or another whether</p> <p>13 scars resulting from burns have nerves in the scar?</p> <p>14 A. Because I -- yes. I don't have experience for</p> <p>15 that.</p> <p>16 MS. THOMPSON: We're out of time, so we'll</p> <p>17 stop.</p> <p>18 THE VIDEOGRAPHER: Off the record 12:58.</p> <p>19 This concludes tape number two.</p> <p>20 (Lunch recess.)</p> <p>21 THE VIDEOGRAPHER: On the record 2:25.</p> <p>22 This begins tape number two.</p> <p>23 MS. THOMPSON: Hello, Dr. Zheng.</p> <p>24 THE WITNESS: Hi.</p> <p>25</p>

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<p>1 (By Ms. Thompson)</p> <p>2 Q. We are -- I'm on page 6 of your report.</p> <p>3 A. Okay.</p> <p>4 Q. It begins with opinions on tissue response to</p> <p>5 TVT-O.</p> <p>6 A. All right.</p> <p>7 Q. I believe either you or Mr. Snell stated this</p> <p>8 morning that you will not be giving opinions as to</p> <p>9 whether the TVT-O is the standard of care; is that</p> <p>10 correct?</p> <p>11 A. How this happens regarding or what's the</p> <p>12 criteria to make TVT or TVT-O as the standard of care I</p> <p>13 think I'm not going to -- I'm not expert for the clinical</p> <p>14 aspects.</p> <p>15 However, this is the fact based on my</p> <p>16 understanding. Ethicon's TVT and TVT-O are still being</p> <p>17 considered as the standard of care for stress urinary</p> <p>18 incontinence.</p> <p>19 Q. But you will not be offering any opinions to</p> <p>20 that effect at trial, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And you state in this section that you've seen</p> <p>23 many meshes removed from asymptomatic patients. We</p> <p>24 talked about that this morning, correct?</p> <p>25 A. Correct.</p>	<p>1 A. Correct.</p> <p>2 Q. What is your basis for saying that mesh</p> <p>3 erosion with TVT and TVT-O is rare?</p> <p>4 Well, is your basis the article that's</p> <p>5 cited in your paper?</p> <p>6 A. Correct. One is the paper cited. The other</p> <p>7 is noncited publications. They also mentioned overall</p> <p>8 infection rate or erosion rate is low.</p> <p>9 Q. Okay. Well, you actually say the erosion rate</p> <p>10 is rare?</p> <p>11 A. Right.</p> <p>12 Q. What's your definition of rare?</p> <p>13 A. Rare cases are occasional cases, basically.</p> <p>14 That's so-called rare. And what's the percentage?</p> <p>15 Maybe, you know, two or less than two or five, less than</p> <p>16 five, those cases.</p> <p>17 Q. Five percent?</p> <p>18 A. Percent, right.</p> <p>19 Q. So less than five percent would be rare, in</p> <p>20 your estimation?</p> <p>21 A. Or can be, yes. Can be basically -- there's a</p> <p>22 loose definition for those conditions. Not like</p> <p>23 people -- everybody understands five or less is rare or</p> <p>24 two or less is rare. Right? So this is -- these</p> <p>25 numerical numbers I think does not give you definitive</p>
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<p>1 Q. And the next line, meshes taken out of</p> <p>2 patients with erosion. What do those meshes typically</p> <p>3 show?</p> <p>4 MR. SNELL: Form.</p> <p>5 A. Grossly, these specimens show not much</p> <p>6 difference from those meshes without erosion.</p> <p>7 (By Ms. Thompson)</p> <p>8 Q. And microscopically?</p> <p>9 A. Microscopically, the mesh with erosions</p> <p>10 typically will show more inflammation or more prominent</p> <p>11 inflammation. Particularly acute component as well as</p> <p>12 abscess formations.</p> <p>13 Q. And those meshes, would you agree, probably</p> <p>14 have evidence of infection?</p> <p>15 A. Yeah. If I see those meshes with abscess</p> <p>16 formation, then probably go along with some kind of</p> <p>17 infection in the clinical aspect.</p> <p>18 Q. And you would actually expect infection with a</p> <p>19 mesh that's been exposed to the vagina, correct?</p> <p>20 MR. SNELL: Form.</p> <p>21 A. Yeah. Many of those conditions associated</p> <p>22 with infection, that's true.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. Because they have, in your words, come in</p> <p>25 contact with the outside world?</p>	<p>1 kind of definitions for the answers you are looking for,</p> <p>2 I think.</p> <p>3 Q. Does the article that you cited, the Ogah</p> <p>4 article, state that erosion is rare?</p> <p>5 A. I believe so.</p> <p>6 (Marked for Identification:</p> <p>7 Deposition Exhibit No. 7)</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. I will go ahead and mark Exhibit 7, which is</p> <p>10 that review article, and if you could just find me the</p> <p>11 part of that article that states that erosion with TVT</p> <p>12 and TVT-O is rare.</p> <p>13 MR. SNELL: What number was this?</p> <p>14 MS. THOMPSON: That was 7.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. What we might want to do is let you look at</p> <p>17 that at a break, if you don't mind, Dr. Zheng --</p> <p>18 A. Sure.</p> <p>19 Q. -- just so we don't take up too much time --</p> <p>20 A. Okay.</p> <p>21 Q. -- if that's okay with you.</p> <p>22 A. Sure.</p> <p>23 Q. On page 7 of your report --</p> <p>24 A. Yes.</p> <p>25 Q. -- appropriate tissue integration --</p>

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<p>1 A. Yes.</p> <p>2 Q. -- you agree that nerve fibers do integrate</p> <p>3 into the mesh pores, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And when you say without mature scar</p> <p>6 formation, what do you mean by that?</p> <p>7 A. Mature scar, as I think we discussed earlier,</p> <p>8 it's composed by pure collagen bundles without vessels,</p> <p>9 typically, or without viable vessels or circulating</p> <p>10 vessels, vessels with circulation. Okay? And that's the</p> <p>11 condition, by definition. And you can see very rare</p> <p>12 maybe. Typically no viable cells. You can see very rare</p> <p>13 cells there.</p> <p>14 Q. So the scar that you see in the mesh pores is</p> <p>15 immature scar?</p> <p>16 A. It's usually there is -- people usually don't</p> <p>17 use sort of immature scar. Scar formation is a process.</p> <p>18 All right? Yes. Beginning from immature and then become</p> <p>19 mature, fully mature. Okay. That's a process.</p> <p>20 Process within this process, you have</p> <p>21 fibrosis. And degree of fibrosis, as we discussed, you</p> <p>22 have mild degree -- or no degree, mild degree, moderate</p> <p>23 degree and severe or extensiveness of the fibrosis,</p> <p>24 different degrees. Then to the extreme then become</p> <p>25 mature scar.</p>	<p>1 MR. SNELL: Form. Outside the scope of</p> <p>2 his opinion.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. You can answer.</p> <p>5 A. Okay. I think all these clinical</p> <p>6 complications mainly in the clinical side. Okay. From</p> <p>7 pathology or pathologist perspective, I'm not really in</p> <p>8 a position to address individual complications.</p> <p>9 But my overall impression for the mesh</p> <p>10 implantation procedures, like a TVT or TVT-O, the overall</p> <p>11 complication rate is low or is within acceptable range in</p> <p>12 medical practice.</p> <p>13 Q. So the opinion that -- or the sentence that my</p> <p>14 opinion is supported by the numerous clinical trials</p> <p>15 showing good performance and low complication rates with</p> <p>16 TVT-O, you will not testify to the good performance and</p> <p>17 low complication rates; is that correct?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. Yeah. I'm not going to testify on the</p> <p>20 clinical side.</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. Okay. You state that multiple animal studies</p> <p>23 demonstrate TVT-O's sufficient pore size. Do you believe</p> <p>24 that to be the case?</p> <p>25 A. Yeah. Because from animal study also you see</p>
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<p>1 And then why we want to do that? Mainly</p> <p>2 because that's related to the function. If you have a</p> <p>3 mature scar, then typically the tissue lost elasticity</p> <p>4 function. Therefore, these area may, you know, inference</p> <p>5 the function, overall organ or tissue function for that</p> <p>6 particular area.</p> <p>7 But while, in contrast, if you have very</p> <p>8 mild or just mild, even some degree of moderate fibrosis</p> <p>9 that's within the process of scar formation, then an end</p> <p>10 result there's no inference for function. So that's the</p> <p>11 difference.</p> <p>12 That's why when we say scar, many people</p> <p>13 use the scar concept is too general. As soon as they see</p> <p>14 little bit fibrosis, they say, oh, this is scar. That's</p> <p>15 not true. Because in our general understanding, when you</p> <p>16 say scar, the basically inference or indicating the</p> <p>17 functional change. While you say fibro-connective tissue</p> <p>18 or the soft tissue with fibrosis, that means, yes, we see</p> <p>19 fibrotic process. However, the function maintains.</p> <p>20 That's underlining, you know, inference.</p> <p>21 Q. Does immature scar eventually develop into</p> <p>22 mature scar?</p> <p>23 A. To certain degree they may develop. It's not</p> <p>24 always develop into mature scar.</p> <p>25 Q. Are mesh complications underreported?</p>	<p>1 these good tissue integration into the mesh pores.</p> <p>2 Therefore, that represent good tissue integration.</p> <p>3 Q. And wouldn't you agree with me that in order</p> <p>4 to extrapolate the results of the animal studies, it</p> <p>5 would need to be implanted in the same tissue as it is</p> <p>6 going to be in in the woman and that it would have to be</p> <p>7 left in for a long term to be able to make that</p> <p>8 assessment?</p> <p>9 A. Sure. Many studies like animal studies the</p> <p>10 animal level, but it does not necessarily say the</p> <p>11 successfulness in the animal study will be also</p> <p>12 successful in the human, you know, implantation. That's</p> <p>13 different thing.</p> <p>14 Q. Okay. So the fact that, of the three animal</p> <p>15 studies that you listed, one was 10 weeks, one was 91</p> <p>16 days, and one was 13 weeks, that's sufficient to show</p> <p>17 that there's appropriate tissue ingrowth?</p> <p>18 A. Yes.</p> <p>19 Q. On page 8, isn't it true that cultures are the</p> <p>20 method that you typically diagnose infection with, not</p> <p>21 histology?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. You mean how to make the diagnosis for</p> <p>24 infection?</p> <p>25</p>

<p style="text-align: right;">Page 114</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Yes.</p> <p>3 A. Infection diagnosis is two things. In the</p> <p>4 tissue level, you see very extensive inflammation,</p> <p>5 including abscess formation, number one.</p> <p>6 Number two is either in the culture or</p> <p>7 special stainings for some microorganisms, then you can</p> <p>8 do that.</p> <p>9 Q. Did you do any special staining for</p> <p>10 microorganisms in Mrs. Edwards?</p> <p>11 A. No. Because there is no reason to do that.</p> <p>12 Q. What is your basis for saying that</p> <p>13 Ms. Edwards did not have an infection in her explanted</p> <p>14 mesh?</p> <p>15 A. Because I did not see extensive inflammation.</p> <p>16 Only the degree of inflammation is mild. And many other</p> <p>17 areas a couple of millimeter away from the mesh material</p> <p>18 even without any evidence of inflammation.</p> <p>19 Therefore, from those tissue sections,</p> <p>20 even you do culture or do stainings, it's unlikely you</p> <p>21 demonstrate these microorganism which may be meaningful</p> <p>22 for indicating infection. Plus, clinically there is no</p> <p>23 evidence of infection anywhere.</p> <p>24 Q. But when there's exposure, there's probably</p> <p>25 infection, correct?</p>	<p style="text-align: right;">Page 116</p> <p>1 infection or subclinical infection.</p> <p>2 Q. And you're also familiar with the term of</p> <p>3 bacterial contamination?</p> <p>4 A. Yes.</p> <p>5 Q. Or colonization?</p> <p>6 A. Yes.</p> <p>7 Q. And you could not say that Ms. Edwards did not</p> <p>8 have one of those conditions; you're talking about she</p> <p>9 did not have an acute infection or an abscess, correct?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. Correct.</p> <p>12 (By Ms. Thompson)</p> <p>13 Q. And you did not perform any cultures on</p> <p>14 Ms. Edwards' mesh, did you?</p> <p>15 A. No. Because what I have received is the block</p> <p>16 within the paraffin and also the slides already cutted.</p> <p>17 So from those conditions are not suitable for culture.</p> <p>18 Q. Moving on to page 9, you state that it would</p> <p>19 be abnormal if no nerve fibers were found in the vaginal</p> <p>20 wall. I think we covered that, right, this morning?</p> <p>21 A. Correct.</p> <p>22 Q. Because the vaginal wall actually has dense</p> <p>23 nerve fibers, correct?</p> <p>24 A. Yes.</p> <p>25 Q. In the second paragraph it states that vaginal</p>
<p style="text-align: right;">Page 115</p> <p>1 MR. SNELL: Form. Misstates.</p> <p>2 A. If the patient has erosion or mesh exposure,</p> <p>3 there is a possibility of infection. However, it's not</p> <p>4 always have infection. This is just like we have a wound</p> <p>5 cut, like on skin, exposed. There is a risk for</p> <p>6 infection. But many of the skin just heal, because we</p> <p>7 have our own immune system to defend.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. And by infection, are you talking about</p> <p>10 abscess?</p> <p>11 A. Yes. The majority pathological presentation</p> <p>12 is abscess formation.</p> <p>13 Q. Are you aware of studies that show that</p> <p>14 100 percent of explanted meshes with erosion have</p> <p>15 bacterial contamination?</p> <p>16 MR. SNELL: Form and foundation.</p> <p>17 A. Bacteria contamination is not necessary or</p> <p>18 equal to the infection, because within the normal vagina,</p> <p>19 we all know there is bacteria there. Therefore, if you</p> <p>20 have exposed, exposed to bacteria, but it's not necessary</p> <p>21 to have the infection.</p> <p>22 (By Ms. Thompson)</p> <p>23 Q. Are you familiar with the term subclinical or</p> <p>24 chronic infection?</p> <p>25 A. Yes. We have chronic -- condition for chronic</p>	<p style="text-align: right;">Page 117</p> <p>1 pain is a clinical symptom. Would you read the last</p> <p>2 sentence in that paragraph and explain that to me,</p> <p>3 please?</p> <p>4 A. That's on page what?</p> <p>5 Q. Page 9. The sentence that begins, Without</p> <p>6 evidence of nerve abnormality.</p> <p>7 A. Which paragraph?</p> <p>8 Q. On page 9, the second paragraph.</p> <p>9 A. Of the normal --</p> <p>10 Q. I want you to read the last sentence.</p> <p>11 A. Okay. Without evidence of nerve abnormality,</p> <p>12 finding nerve fibers in vaginal mesh does not correlate</p> <p>13 to the clinical symptom of vaginal pain or dyspareunia.</p> <p>14 Q. Isn't it true that normal nerves are what</p> <p>15 cause pain, not abnormal nerves?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. No. I think, you know, many general people</p> <p>18 believe all the pain sensation are generated by nerve.</p> <p>19 As I think we briefly discussed, pain feeling is a</p> <p>20 complicated process. All right? Many of them, they may</p> <p>21 be related to nerve sensation, but many of them they are</p> <p>22 also not related to a nerve.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. But as far as mesh goes, are you saying that</p> <p>25 if you do -- don't -- if you can't demonstrate nerve</p>

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<p>1 abnormality, that you can't correlate the clinical</p> <p>2 symptom of vaginal pain and dyspareunia to the mesh?</p> <p>3 A. Because from pathological perspective, if I</p> <p>4 see some nerve abnormalities, then that may support the</p> <p>5 clinical finding or clinical complaint of pain from that</p> <p>6 area. However, if I don't have such evidence, then I</p> <p>7 can't correlate this kind of complaint.</p> <p>8 But I didn't say her or anyone complains</p> <p>9 of pain is not true, because pain is a feeling. It's a</p> <p>10 personal experience. These are totally different</p> <p>11 concepts.</p> <p>12 Q. Isn't it true that abnormal nerves typically</p> <p>13 cause numbness or paralysis or other symptoms, not pain?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. No. For instance, abnormal nerve, including</p> <p>16 neuroma, is a tumor-like lesion, clusters of</p> <p>17 abnormal-looking nerve fibers coming together. Then this</p> <p>18 is well documented phenomenon can generate pain.</p> <p>19 For instance, someone -- if my finger get</p> <p>20 a cut, then that -- after cutting the portion of the</p> <p>21 finger, the end of the -- proximal end of the nerve may</p> <p>22 form a neuroma-like lesion. Then that area will generate</p> <p>23 pain. That's histological convincing evidence.</p> <p>24 (By Ms. Thompson)</p> <p>25 Q. Has anyone, either treating physicians or</p>	<p>1 Q. And would the same be true if you're looking</p> <p>2 for a perineural invasion with a malignant tumor?</p> <p>3 A. Yes. Perineural invasion with cancers are</p> <p>4 then we usually do not stain with nerve-like markers. We</p> <p>5 just identify cancer cells, because typical nerve fibers,</p> <p>6 they are easily identifiable under microscope.</p> <p>7 Q. So with H&E stain?</p> <p>8 A. With H&E.</p> <p>9 Q. So the competent, experienced pathologist can</p> <p>10 see nerves? You don't have to rely on any special</p> <p>11 staining to see nerves; is that correct?</p> <p>12 A. Correct.</p> <p>13 Q. Does chronic inflammation cause cancer?</p> <p>14 A. That's another very general question. All</p> <p>15 right. Many cancers can be associated with chronic</p> <p>16 inflammation. But whether chronic inflammation directly</p> <p>17 cause cancer probably is not a good statement.</p> <p>18 Q. So it's an association more than cause and</p> <p>19 effect, in your opinion?</p> <p>20 A. Yes. Overall in the field that's...</p> <p>21 Q. Why can rat studies on sarcoma formation not</p> <p>22 be extrapolated to the human experience?</p> <p>23 A. As I said, animal studies represent in animal</p> <p>24 levels, and then if -- you have to find evidence in the</p> <p>25 human to see if this kind of condition can be repeatable.</p>
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<p>1 experts that you're aware of, given the opinion that</p> <p>2 either Mrs. Huskey or Mrs. Edwards have a neuroma?</p> <p>3 A. I don't see their reports mention that. But</p> <p>4 based on my examination from Edwards, I don't see any</p> <p>5 evidence of neuroma.</p> <p>6 Q. In the cancer section --</p> <p>7 A. Yes.</p> <p>8 Q. Well, what is your definition of neuroma?</p> <p>9 A. Neuroma is defined by the collection of nerve</p> <p>10 or nerve fiber sheaths, okay, then forming a tumor-like</p> <p>11 lesion, so-called neuroma.</p> <p>12 Q. Do they have to be a certain number of nerves</p> <p>13 or a certain density of nerves?</p> <p>14 A. Yes. Should be lot more than the normal</p> <p>15 distribution in adjacent tissue. You can use adjacent</p> <p>16 tissue as a reference to compare.</p> <p>17 Q. What stain do you use to diagnose a neuroma?</p> <p>18 A. What?</p> <p>19 Q. What stain?</p> <p>20 A. Oh. We usually we don't need to stain because</p> <p>21 neuroma under microscope you see lots of nerve structures</p> <p>22 there.</p> <p>23 Q. So you're able to identify the nerves with</p> <p>24 H&E?</p> <p>25 A. Correct.</p>	<p>1 And for mesh implant into woman, so far,</p> <p>2 based on my understanding so far, I don't see any</p> <p>3 publications saying mesh within any humans cause this</p> <p>4 kind of cancer formation so far.</p> <p>5 Q. That would be good to know, though, wouldn't</p> <p>6 it, before you placed a permanent implant in a human?</p> <p>7 A. It's not really necessary, because usually</p> <p>8 even in the animal studies, you don't see too many cancer</p> <p>9 formation or models. There is no established model that</p> <p>10 says with this kind of mesh material you can constantly</p> <p>11 or repeatedly can generate these cancers or malignancy.</p> <p>12 Q. What would be the latency period for mesh if</p> <p>13 it were to cause cancer?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. There is no data. Nobody knows, because there</p> <p>16 is no such report.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. So there's really no data on whether</p> <p>19 polypropylene causes cancer or not in a human?</p> <p>20 MR. SNELL: Form. Misstates.</p> <p>21 A. I think so far we shall say there is data --</p> <p>22 not any data stating or saying the mesh is related to the</p> <p>23 cancer formation.</p> <p>24 (By Ms. Thompson)</p> <p>25 Q. Are you aware of reports of cancer associated</p>

<p style="text-align: right;">Page 122</p> <p>1 with mesh in the abdominal wall?</p> <p>2 A. I'm not aware of that.</p> <p>3 Q. Are you aware of studies showing benign</p> <p>4 inflammatory tumors associated with vaginal mesh?</p> <p>5 MR. SNELL: Form. Go ahead. Foundation</p> <p>6 on that question.</p> <p>7 A. There is no such entity called benign</p> <p>8 inflammatory tumor, because there is no such a thing</p> <p>9 there. You can have a benign tumor, and then</p> <p>10 inflammation may be related to that. Then -- or</p> <p>11 tumor-like conditions may be associated with</p> <p>12 inflammation.</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. What is an inflammatory myofibroblastic tumor</p> <p>15 of the urinary tract?</p> <p>16 A. That's kind of one of the rare tumors, you</p> <p>17 know, associated with inflammation.</p> <p>18 Q. Sounds like an inflammatory tumor. Am I</p> <p>19 right?</p> <p>20 MR. SNELL: Form.</p> <p>21 A. Well, that's why -- but what I mean for your</p> <p>22 previous statement is there is no -- nobody calls benign</p> <p>23 inflammatory tumors in the GYN system.</p> <p>24 (By Ms. Thompson)</p> <p>25 Q. So I should have left out the benign and just</p>	<p style="text-align: right;">Page 124</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. I will mark as Exhibit 8 photographs of the</p> <p>3 block that I believe -- the blocks that I believe you</p> <p>4 received.</p> <p>5 A. Yes.</p> <p>6 Q. To your best knowledge or recollection, would</p> <p>7 these be Tonya Edwards' blocks?</p> <p>8 A. Yes.</p> <p>9 Q. And the mesh in these blocks appear...</p> <p>10 (Marked for Identification:</p> <p>11 Deposition Exhibit No. 9)</p> <p>12 (By Ms. Thompson)</p> <p>13 Q. I will also mark as Exhibit 9 the gross</p> <p>14 pictures of the mesh received from Tonya Edwards,</p> <p>15 photographed by the plaintiffs' expert, Dr. Iakovlev.</p> <p>16 A. Okay.</p> <p>17 Q. And would you agree with me that the mesh that</p> <p>18 you received in block is not fragmented?</p> <p>19 A. Is not fragmented?</p> <p>20 Q. Correct.</p> <p>21 A. When they embed, yes, they embed those gross</p> <p>22 tissues with mesh, probably do not represent too many</p> <p>23 sections. Just they put, you know, these fragments of</p> <p>24 tissue with mesh, then embed it into block, two blocks</p> <p>25 labeled with A and B, I think, either one of them.</p>
<p style="text-align: right;">Page 123</p> <p>1 said inflammatory tumor, correct?</p> <p>2 A. Yeah. It's a very loose kind of term to</p> <p>3 describe the condition. It's actually is like a tumor or</p> <p>4 tumor-like conditions or tumor, benign tumor. Then later</p> <p>5 on has associated with inflammation. It's not a real</p> <p>6 good entity for that.</p> <p>7 Q. Gotcha. Moving on to your opinions specific</p> <p>8 to plaintiff Tonya Edwards beginning on page 10.</p> <p>9 A. Okay.</p> <p>10 Q. Tell me what exactly you received when you got</p> <p>11 the pathology in this case.</p> <p>12 A. I received some H&E slides from the two blocks</p> <p>13 of Tonya Edwards, from the patient. Okay? Then H&E</p> <p>14 slides, then four slides stained with S100. Okay? I</p> <p>15 think those are the material basically I received.</p> <p>16 Q. So that was a total of 17 slides; is that</p> <p>17 correct?</p> <p>18 A. I think so.</p> <p>19 Q. Okay. And then you also received two blocks;</p> <p>20 is that correct?</p> <p>21 A. Correct.</p> <p>22 Q. And would this...</p> <p>23 (Marked for Identification:</p> <p>24 Deposition Exhibit No. 8)</p> <p>25</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. But you would agree with me that the mesh in</p> <p>2 block resembles the mesh taken from the formalin?</p> <p>3 A. More or less in general, yes, resembles that.</p> <p>4 Q. And the -- how many sections can you get out</p> <p>5 of a three-millimeter block of tissue?</p> <p>6 A. Three-millimeter block of tissue, you see, if</p> <p>7 continuous cutting without waste anything, in general we</p> <p>8 have five-micron tissue, right? Five micron, then if you</p> <p>9 have three millimeter, that means 3,000 micron. So if</p> <p>10 you divide by five, you can -- in theory, you can have a</p> <p>11 lot.</p> <p>12 However, in reality, when these blocks</p> <p>13 being cut, you have to put them in the same plane. Then</p> <p>14 you cut a nice section. So, therefore, histology</p> <p>15 technician, they have to adjust the block plane, then</p> <p>16 have to trim the tissue. You understand what I'm</p> <p>17 talking?</p> <p>18 Q. So if each section was four micrometers --</p> <p>19 A. No.</p> <p>20 MR. SNELL: No.</p> <p>21 A. Four to five micron. Classically, in our</p> <p>22 institution, five micron. Then some institutions use</p> <p>23 four micron, that's true.</p> <p>24 (By Ms. Thompson)</p> <p>25 Q. Okay. And then you have a little bit of space</p>

<p style="text-align: right;">Page 126</p> <p>1 in between?</p> <p>2 A. Then not -- depending on not -- like little</p> <p>3 bit of space, because typically technicians has a habit</p> <p>4 to trim the tissue, because the block is very flat on a</p> <p>5 surface. So at the beginning when the block was made,</p> <p>6 it's not flat and smooth, so has uneven surface. So the</p> <p>7 technician has to make this even and smooth surface; they</p> <p>8 have to trim the tissue block.</p> <p>9 From that point of view, then some of the</p> <p>10 tissue will have to be wasted. Otherwise never to cut a</p> <p>11 single plane or single section contains every piece of</p> <p>12 tissue. You understand, right? Because when you embed,</p> <p>13 they are not in the same plane.</p> <p>14 Q. So if Dr. Iakovlev's lab did eight sections</p> <p>15 from one block, nine sections from the other block, did</p> <p>16 not waste any more than what is required to do the</p> <p>17 sections, that would be approximately 1,500 sections in</p> <p>18 each block, correct?</p> <p>19 MR. SNELL: Form.</p> <p>20 A. That's why I said, in theory, yes, you can --</p> <p>21 each block can generate lots of sections, that's true.</p> <p>22 But in reality, reality makes difference, because nothing</p> <p>23 in practical conditions. You can just based on theory,</p> <p>24 then general things.</p> <p>25 So, in reality, let me explain to you.</p>	<p style="text-align: right;">Page 128</p> <p>1 depending on one level to the other level usually if it's</p> <p>2 continuous, then these levels almost identical or with</p> <p>3 very minimal changes. But, in reality, when I examined</p> <p>4 parallel levels from -- because each block he generated</p> <p>5 several levels, right? You understand, right?</p> <p>6 Q. Correct.</p> <p>7 A. Even in the S100 staining sections, they are</p> <p>8 parallel levels. Within these two parallel levels from,</p> <p>9 for instance, block A, then they look dramatically</p> <p>10 different. Therefore, something is missing in between.</p> <p>11 That means in most of the conditions the technician have</p> <p>12 a habit generally do one slide, then cut more, throw it</p> <p>13 away, and take another section.</p> <p>14 Q. So you had all the slides that Dr. Iakovlev</p> <p>15 made, correct?</p> <p>16 A. Correct.</p> <p>17 MR. SNELL: Hold on, hold on. I'm going</p> <p>18 to object on foundation. He doesn't know that. We don't</p> <p>19 know what Dr. Iakovlev has. We only have what he has</p> <p>20 produced. And the doctor has already testified there's</p> <p>21 stuff missing, so...</p> <p>22 MS. THOMPSON: I don't believe that's the</p> <p>23 case.</p> <p>24 MR. SNELL: Did you not testify that</p> <p>25 there's --</p>
<p style="text-align: right;">Page 127</p> <p>1 For instance, from this, these gross specimens, tissue</p> <p>2 size are different, right? See that fragment is long,</p> <p>3 and the other is small. Then the thickness, they are</p> <p>4 different. See the thickness? Some of them quite thick;</p> <p>5 some of them quite flat. All right?</p> <p>6 And then when you embed, they are not in</p> <p>7 the ideal everything the same level. When the technician</p> <p>8 embedded these tissue fragments into paraffin block, they</p> <p>9 are in sort of similar even level but not identical. You</p> <p>10 understand, right? Do you?</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. Yes, I do.</p> <p>13 A. And then when they make these blocks, you see,</p> <p>14 their surface is very flat. How that happen? They have</p> <p>15 to trim, make these things even. Then to expose every</p> <p>16 fragment of tissue, then can place them on a slide.</p> <p>17 So in between this kind of process, you</p> <p>18 have to trim a lot, make them even. So that process</p> <p>19 maybe 20, 25 percent of tissue will be wasted already.</p> <p>20 Otherwise we never reach to the same level in a single</p> <p>21 slide.</p> <p>22 Q. Dr. Iakovlev took 17 sections, and there are</p> <p>23 potentially 3,000 in those blocks. You have a little bit</p> <p>24 of latitude, don't you?</p> <p>25 A. I understand that. Then, additionally,</p>	<p style="text-align: right;">Page 129</p> <p>1 MS. THOMPSON: Oh, I thought you meant</p> <p>2 Dr. Iakovlev. Okay.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. So what we do know, you had 17 slides from</p> <p>5 Dr. Iakovlev. You had these two blocks that generally</p> <p>6 correspond with the gross picture that Dr. Iakovlev took.</p> <p>7 We have potentially 3,000 sections in each, in the two</p> <p>8 blocks combined.</p> <p>9 A. I didn't say 3,000.</p> <p>10 MR. SNELL: He didn't say that.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. I'm finishing. I'm saying potentially. I'm</p> <p>13 saying that.</p> <p>14 He says they're four and you say they're</p> <p>15 five, so that could be a little less for that reason.</p> <p>16 And you actually were able to cut much deeper into the</p> <p>17 block than Dr. Iakovlev did, correct?</p> <p>18 MR. SNELL: Hold on. Form. That's</p> <p>19 compound on multiple levels. Two, misstates his prior</p> <p>20 testimony. He didn't agree there were 3,000. And</p> <p>21 foundation, there's a foundation issue.</p> <p>22 Go ahead.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. I think the question on the table is you were</p> <p>25 able to cut deeper into the block than Dr. Iakovlev,</p>

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<p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. But are you telling me today that you did not</p> <p>4 have enough of the mesh to properly evaluate Ms. Edwards'</p> <p>5 case?</p> <p>6 A. I didn't say that. I said, you know, I have</p> <p>7 cut like three slides from each block. Okay? Then I</p> <p>8 used one of them to perform neurofilament staining.</p> <p>9 Neurofilament staining. Okay?</p> <p>10 And then within these two stained slides,</p> <p>11 I have seen tissue fragmentation. That's the fact.</p> <p>12 Q. But you did have enough specimen to make your</p> <p>13 diagnosis with Ms. Edwards, correct?</p> <p>14 A. To make the staining, basically. Because</p> <p>15 Dr. Iakovlev already provide multiple level of H&E</p> <p>16 slides, I have no reason to repeat those.</p> <p>17 Q. So you had sufficient material --</p> <p>18 A. To evaluate.</p> <p>19 Q. -- to evaluate?</p> <p>20 A. That's right.</p> <p>21 Q. And, in fact, the deeper cuts that you did</p> <p>22 actually showed the area of erosion into the vagina,</p> <p>23 correct?</p> <p>24 A. No.</p> <p>25 MR. SNELL: Form.</p>	<p>1 MR. SNELL: Form.</p> <p>2 Go ahead.</p> <p>3 A. Yes. I did find mild fibrosis and mild degree</p> <p>4 of chronic inflammation and a few foreign body giant</p> <p>5 cells.</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. And are those findings typical of the other</p> <p>8 mesh specimens that you have examined over the years?</p> <p>9 A. Correct. They are quite typical.</p> <p>10 Q. Looking at the slide -- and in your opinion,</p> <p>11 this is appropriate tissue integration, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Looking at the photomicrograph on page 13 with</p> <p>14 the exposure, you would not say that's appropriate tissue</p> <p>15 integration, would you?</p> <p>16 MR. SNELL: Form. Objection.</p> <p>17 I think you misstated.</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. Erosion into the vagina, is that appropriate</p> <p>20 tissue integration?</p> <p>21 MR. SNELL: Same objection. Foundation on</p> <p>22 erosion.</p> <p>23 A. First of all, I think I would like to clarify.</p> <p>24 I said here you have squamous mucosa disruption. That</p> <p>25 means noncontinuous. Do you see that on the surface? So</p>
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<p>1 A. I did not evaluate the erosion issues for the</p> <p>2 sections, for the pictures I provided. These pictures</p> <p>3 are from the slides I receive from Iakovlev.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. So on page 13, that's a slide provided to you</p> <p>6 by Dr. Iakovlev?</p> <p>7 A. Correct. All the H&E pictures were from</p> <p>8 original slides that he send to me.</p> <p>9 Q. So the only additional stains you did were the</p> <p>10 neurofilament?</p> <p>11 A. The neurofilament.</p> <p>12 Q. And everything else was what you received, the</p> <p>13 H&E?</p> <p>14 A. Correct.</p> <p>15 Q. And S100 from Dr. Iakovlev?</p> <p>16 A. Correct.</p> <p>17 Q. All right. And I believe you said earlier</p> <p>18 that typically you would not see an explanted mesh until</p> <p>19 you received the slides. So this case was your standard</p> <p>20 operating procedure, basically, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Are the findings in Ms. Edwards, specifically</p> <p>23 chronic inflammation, fibrosis and foreign body reaction</p> <p>24 -- well, first of all, are those your findings in Tonya</p> <p>25 Edwards' mesh?</p>	<p>1 this is the description. I did not make a conclusion,</p> <p>2 what does it mean. Okay?</p> <p>3 Then the second thing is underneath of</p> <p>4 this mucosa, you can see these whitish spaces. That area</p> <p>5 represent mesh fiber spaces. Therefore, from the mesh</p> <p>6 fiber spaces to the mucosa is quite close. It's about</p> <p>7 one to two millimeter distance. Do you see that?</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. I'm going to hand you a larger picture --</p> <p>10 A. Okay.</p> <p>11 Q. -- of the one that appears in your report on</p> <p>12 page 13.</p> <p>13 A. Sure.</p> <p>14 Q. And this will be Exhibit Number 10.</p> <p>15 MR. SNOWDEN: For the record, that was</p> <p>16 pictures that we provided to you at the deposition?</p> <p>17 MS. THOMPSON: This is one I brought.</p> <p>18 MR. SNOWDEN: Oh, you brought that? Okay.</p> <p>19 I thought this was one of the pictures we provided at the</p> <p>20 deposition.</p> <p>21 MS. THOMPSON: No. I have not looked at</p> <p>22 those yet. I brought this with me.</p> <p>23 MR. SNELL: You're marking it as 10?</p> <p>24 MS. THOMPSON: I'm marking this as 10.</p> <p>25</p>

<p style="text-align: right;">Page 134</p> <p>1 (Marked for Identification: 2 Deposition Exhibit No. 10) 3 (By Ms. Thompson) 4 Q. And would you take that Sharpie and show me, 5 mark on there where the mucosal disruption is. You 6 can -- 7 A. In this area. 8 Q. Okay. You can circle that and put MD. 9 A. MD? 10 Q. Yeah. Yes. For mucosal disruption. 11 A. Oh, okay. 12 Q. And I believe you said those white spaces are 13 where the mesh was? 14 A. Yes. 15 Q. You beat me to it. 16 A. Okay. 17 Q. And is it a normal finding to have mucosal 18 disruption with mesh? 19 MR. SNELL: Form. 20 A. If there is like erosion, yes. You will see 21 mucosal disruption. Or even surface ulceration, you will 22 see that. Okay. 23 But here when I said the disruption, that 24 means noncontinuous mucosa. Noncontinuous mucosa can 25 have multiple reasons. One is maybe associated with</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. Is that normal loose connective tissue that 2 you usually find in the submucosa of the vagina? 3 MR. SNELL: Form. 4 A. I should say in normal vagina you should see, 5 you know, less fibrosis in a normal condition. That's 6 true. But here you have little bit more fibrotic 7 changes. 8 (By Ms. Thompson) 9 Q. Well, you have more fibrotic changes than you 10 would in a normal vagina, correct? 11 A. Correct. 12 Q. And doesn't that rule out artifact or a 13 cutting phenomenon? 14 A. No. Because one existing fact is we have mesh 15 already very close to the mucosa. Okay? Whether this is 16 a normal finding or not, I can't make a judgment, mainly 17 because we know the mesh implantation is from underneath 18 of the mucosa, then to outside. Have to go outside, 19 right? Go through skin area, that area. So some area 20 may be just the placement, original placement is very 21 close to the mucosa. 22 Therefore, when you have those conditions, 23 you can see more fibrotic changes than in the normal 24 condition. That's perfectly fine. 25 Q. So this fibrosis that's penetrating the</p>
<p style="text-align: right;">Page 135</p> <p>1 erosion. All right? 2 Two is maybe represented artifact, because 3 when you cut the tissue, then tissue can be -- you know, 4 the artifact can be generated by the cutting process. 5 And then three is, depending on the 6 mucosal location of the tissue fragment, because as you 7 can see from the gross specimen, these tissue 8 fragmentation or these tissue fragments, they're not 9 even. If one side has little bit -- one side has little 10 bit of mucosa on the tip, then depending on whether it's 11 on the surface or in the bottom when they cut through, 12 then may partially represent discontinuation. 13 So multiple reasons. That's why I 14 describe this finding is there. Then just to show you, 15 you know, this is the area I found. Maybe relevant for 16 this case. 17 (By Ms. Thompson) 18 Q. Okay. So in this picture, you're saying this 19 mucosal disruption can either be vaginal erosion from the 20 mesh, an artifact, or a sequela of the cutting process, 21 correct? 22 A. Yes. 23 Q. What is this pink stuff here? 24 A. This pink stuff basically is submucosal area 25 with more -- little bit more fibrosis.</p>	<p style="text-align: right;">Page 137</p> <p>1 vaginal wall is perfectly fine? 2 A. I think we are talking different things. 3 Whenever -- if you don't have any like mesh 4 implantations, then you do not have this amount of 5 fibrotic changes in those conditions, in general. 6 Q. Okay. 7 A. But now when you have implantation there, yes. 8 Particularly for Edwards case, she has like six years or 9 so amount implant into this area, so you expect to see a 10 certain amount of fibrosis. 11 Q. Would you mind marking the fibrosis with an F. 12 And you have the same fibrosis on the 13 other side, correct? 14 A. You mean this side? 15 Q. On the -- well, where the mesh is. Both areas 16 of the fibrosis. 17 A. Right. This area has less fibrosis. 18 Q. Would you still consider that fibrosis? 19 A. Yes. I already said in my report. I said 20 overall we have mild fibrosis. 21 Q. So are you telling me today that this is -- 22 could be something other than mesh eroding through the 23 vaginal wall? 24 A. Mesh here is very close to the vaginal mucosa 25 or squamous mucosa. That's true. But how that happens,</p>

<p style="text-align: right;">Page 138</p> <p>1 whether it's related to erosion, I think erosion is a</p> <p>2 grossly visible condition. More reliable by clinical</p> <p>3 examination. Therefore, I provide three conditions to</p> <p>4 explain why you have disruption of the mucosa.</p> <p>5 Q. And you know that Tonya Edwards had exposure</p> <p>6 per her surgeon?</p> <p>7 A. I think based on my reading later on, some --</p> <p>8 one area the surgeon says there is exposure. Then later</p> <p>9 on says no exposure. So I'm confused whether it's true</p> <p>10 it has exposure or not. So I'm not in a position to</p> <p>11 testify that part.</p> <p>12 Q. Did you read her operative report of the mesh</p> <p>13 explant?</p> <p>14 A. I think so, I did.</p> <p>15 MS. THOMPSON: And the operative report, I</p> <p>16 will mark this as Exhibit 11.</p> <p>17 (Marked for Identification:</p> <p>18 Deposition Exhibit No. 11)</p> <p>19 (By Ms. Thompson)</p> <p>20 Q. Under findings of the operative report, pelvic</p> <p>21 examination showed eroded mesh along the anterior vaginal</p> <p>22 wall.</p> <p>23 Would that not be important to you as a</p> <p>24 pathologist to know there was erosion?</p> <p>25 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 140</p> <p>1 resulting questions to be answered.</p> <p>2 You're telling me that in a patient that</p> <p>3 clinically has an erosion, you might call this something</p> <p>4 else?</p> <p>5 MR. SNELL: Actually form and foundation.</p> <p>6 You're misstating certainly the record as it appeared.</p> <p>7 MS. THOMPSON: That's the statement that I</p> <p>8 read this morning to him and he agreed with.</p> <p>9 MR. SNELL: No, no, no, no. You're</p> <p>10 talking about how a person goes into the surgery and</p> <p>11 you're trying to apply that to something that was</p> <p>12 supposedly seen during the surgery. That's my objection</p> <p>13 on foundation. I think those are two different things.</p> <p>14 A. So if you want me to make a comment whether</p> <p>15 this go along with erosion, then I said if clinically</p> <p>16 there is a definitive erosion, then the finding is</p> <p>17 consistent with the erosion.</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. But here today you're perfectly willing to say</p> <p>20 that this could be artifact or a cutting --</p> <p>21 A. Because as I said, there is no definitive</p> <p>22 answer for that, because many, you know, situations can</p> <p>23 generate this picture. That's the overall.</p> <p>24 Q. What causes erosion of mesh?</p> <p>25 A. What's the causes for mesh erosion? I think</p>
<p style="text-align: right;">Page 139</p> <p>1 A. Well, somehow my impression, yes, I notice</p> <p>2 there is one place like this saying that. But there is</p> <p>3 other place says, you know, there's no obvious exposure</p> <p>4 or did not mention at least for erosion or exposure.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. Isn't it true that GYN doctors can sometimes</p> <p>7 not see erosion in the office, but when you have a</p> <p>8 patient under anesthesia and you can get better</p> <p>9 visualization, you can see the erosion?</p> <p>10 So the operative note would be the most</p> <p>11 accurate determination, correct?</p> <p>12 MR. SNELL: Form.</p> <p>13 Go ahead.</p> <p>14 A. I don't think I'm, you know, in the position</p> <p>15 to make such a comment, because, in general, maybe this</p> <p>16 is a correct statement. So which one I should believe I</p> <p>17 don't know. This is the situation. If it's truly</p> <p>18 observed some kind of exposure, this may go along with</p> <p>19 that. But as we know, either exposure or erosion is one</p> <p>20 of the complications for mesh implantation.</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. So you, as you sit here today, are telling me</p> <p>23 that -- and I'm going back to this morning when you</p> <p>24 testified that the pathologist's interpretation is based</p> <p>25 on his understanding of the clinical context and</p>	<p style="text-align: right;">Page 141</p> <p>1 I'm the pathologist. I don't know what's the cause for</p> <p>2 erosion. It's better for the clinician to answer.</p> <p>3 But, in general, erosions may be related</p> <p>4 to wound healing in general, okay, number one. And also</p> <p>5 surgical skills. When you put there, you need to have,</p> <p>6 you know, correct surgical procedures. It's not everyone</p> <p>7 just can do this without proper training. Okay?</p> <p>8 And then also related to patient</p> <p>9 lifestyle, okay, because maybe patient, for whatever</p> <p>10 reason, have some kind of injury in that area after</p> <p>11 surgery. Then exposure or erosion may happen. Okay.</p> <p>12 Then patient immune system or immune reactions to see if</p> <p>13 this area is infected or not. If it's infected, also</p> <p>14 will have a risk for invasion.</p> <p>15 Then which factor plays which role? I'm</p> <p>16 not in a position to tell. Basically I'm not able to</p> <p>17 tell. But overall situation are related to those</p> <p>18 so-called erosion-related factors.</p> <p>19 Q. So are those the only factors that come to</p> <p>20 your mind?</p> <p>21 A. I think overall I mentioned all these factors,</p> <p>22 the main factors may contribute to erosion situation.</p> <p>23 Q. All right. So you mentioned the surgeon and</p> <p>24 the placement of the mesh, correct?</p> <p>25 A. Right.</p>

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1 Q. And you mentioned patient characteristics that
2 might make them more prone; is that correct?
3 A. Yes.
4 Q. And you mentioned immune situations also with
5 a patient?
6 A. Right.
7 Q. And you mentioned if the area is infected. I
8 presume you mean infected before you put it in; is that
9 correct?
10 A. Or can be after that.
11 Q. Okay. So infection before or after?
12 A. Right.
13 Q. And that's a patient characteristic as well?
14 A. Right. And then whether patient has local
15 injury, you know, in the mesh area. That also is --
16 actually is more common factor to contribute to erosion.
17 Do you understand?
18 Q. Yes. So the TVT-O device itself does not
19 cause erosion, in your opinion, unless one of those other
20 factors are present?
21 A. I don't think TVT-O itself will cause erosion,
22 because overall erosion rate is so low. If TVT mesh
23 material itself can cause erosion, then I will see more
24 than 50 percent of these patients who receive a TVT will
25 have erosion. Is that correct? You think in general, in

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1 common sense?
2 Q. What's your basis for that opinion?
3 A. Well, as you say, you are asking me --
4 Q. Or is it just common sense?
5 A. Right. It's common sense. If this is bad
6 material will contribute for erosion, then majority of
7 those patients who received mesh implants will have
8 erosion.
9 Q. Does normal tissue have inflammation?
10 A. Normal tissue should not have inflammation.
11 Q. What do you mean by microcapillary vessels?
12 A. Microcapillary vessel means small caliber
13 vessels. Usually measures only in like micron levels,
14 150 to 100 micron levels.
15 Q. Is that a term that's used routinely in the
16 pathological world?
17 A. Yes. It's a common terminology used by
18 pathologists.
19 MS. THOMPSON: The picture on page 14,
20 your Figure 5, we will mark that as Exhibit 12, and
21 that's Figure 5 in your report on page 14.
22 (Marked for Identification:
23 Deposition Exhibit No. 12)
24 (By Ms. Thompson)
25 Q. And you have a copy of your report there as

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1 well --
2 A. Yes.
3 Q. -- correct?
4 You may want to refer to the blowup or the
5 higher magnification, shall I say, of the same picture,
6 because I don't think I have it.
7 Describe to me what you see here on this
8 slide.
9 MR. SNELL: You mean beyond all the stuff
10 he put in Figure 5 that you didn't put on this exhibit?
11 A. So that's basically Figure 5 you want me to
12 describe?
13 MS. THOMPSON: You mean the text?
14 MR. SNELL: Yeah. I'll note for the
15 record this actually has in the report obviously a lot
16 of -- a whole paragraph describing what it is. Are you
17 asking him to read that? Because you didn't copy it.
18 MS. THOMPSON: I'm asking him to mark on
19 the picture --
20 MR. SNELL: That's a different thing.
21 Okay.
22 (By Ms. Thompson)
23 Q. I'm asking you what this shows and to please
24 mark on the picture what you're describing.
25 A. So overall this picture, Figure 5, just shows

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1 minimum or mild degree of fibrosis without scar
2 formation.
3 Q. And so those areas between the mesh pores
4 you're calling mild or mild to moderate fibrosis?
5 A. Minimum or mild fibrosis.
6 Q. Minimum or mild fibrosis and no scar
7 formation?
8 A. And no pure scar here. Basically here the
9 scar means pure collagen bundle or the scar we described.
10 Q. Is pure scar a term that's used in the
11 pathology literature?
12 A. Yes. In general, when we say scar, it means a
13 pure scar or mature scar.
14 Q. So you use pure scar and mature scar
15 synonymously?
16 A. Right. Or just like a scar. When we say
17 scar, it means microscopically refer to those pure
18 clusters of or collection of the collagen bundles.
19 Q. And when you state that there are no pure
20 haphazardly arranged collagen bundles, parenthesis, scar
21 present, is that how you define scar, as haphazardly
22 arranged collagen bundles?
23 A. Correct.
24 Q. What's your basis for that? Where would I
25 find that definition?

<p style="text-align: right;">Page 146</p> <p>1 A. That should be in the general textbook, 2 pathology textbook. 3 Q. I thought scar was laid down in layers so it 4 has a parallel appearance to the collagen? 5 A. It's not necessarily parallel. They are 6 usually randomly arranged. That's the reason they lost 7 the tissue elasticity. Otherwise you should have certain 8 degree of elasticity. 9 Q. So scar does lose elasticity, you would agree? 10 A. Correct. 11 Q. And you think that this definition of 12 haphazardly arranged collagen bundles I would find in a 13 pathology textbook as a definition of scar? 14 A. I think so. You should be able to do that. 15 Q. Is -- did you say scar and fibrosis are the 16 same thing? 17 A. No. I said that they are different. Fibrosis 18 you have different degrees. And scar is a mature or pure 19 collagen bundles. Two different concepts. 20 Q. Is Robbins and Cotran an authoritative 21 pathology textbook, in your opinion? 22 A. That's -- yes. That's mainly for medical 23 students. 24 Q. In fact, would some people say that's the 25 bible of pathology?</p>	<p style="text-align: right;">Page 148</p> <p>1 have -- give to quantify. When you have everywhere it's 2 all fibrotic, I mean, severe, extensive, then the 3 equivalent to scar. 4 Q. So you disagree with the bible of pathology on 5 that one? 6 MR. SNELL: Form, foundation. 7 MS. THOMPSON: I asked him a question. 8 MR. SNELL: You called it a bible. He 9 didn't say it was a bible. He certainly didn't agree 10 that it was the bible. What you read to him doesn't say 11 who refers to it simultaneously. He certainly doesn't. 12 A. I can disagree particular sentence. I didn't 13 disagree the whole textbook. I disagree actually many of 14 them in the GYN section, because they were written by 15 non-GYN experts in that book. 16 MS. THOMPSON: We can break. 17 THE VIDEOGRAPHER: Off the record 3:39. 18 This concludes tape number three. 19 (Recess taken.) 20 THE VIDEOGRAPHER: On the record 3:50. 21 This begins tape number four. 22 (Marked for Identification: 23 Deposition Exhibit No. 13) 24 (By Ms. Thompson) 25 Q. Dr. Zheng, if you would turn to page 17 of</p>
<p style="text-align: right;">Page 147</p> <p>1 MR. SNELL: Foundation, form. Who are 2 these people? 3 A. Some people may refer that heavily from 4 medical students' point of view, yes. 5 (By Ms. Thompson) 6 Q. So it's referenced heavily, and you'd 7 considered it authoritative, correct? 8 MR. SNELL: Misstates. Form. 9 A. I should say this is a quite familiar 10 textbook. If you went to medical school in United 11 States, or Europe even, many people are familiar with 12 this textbook, that's true. 13 (By Ms. Thompson) 14 Q. The definition from Robbins and Cotran, I'll 15 read it to you: The term scar is most often used in 16 connection to wound healing in the skin, but is also used 17 to describe the replacement of parenchyma cells in any 18 tissue by collagen. 19 Would you agree with it? 20 A. Yes. That's the so-called collagen here, 21 right? 22 Q. And another quote from that same textbook is 23 the terms scar and fibrosis are used interchangeably. 24 Would you agree with that? 25 A. No. Because, as I said, fibrosis you have to</p>	<p style="text-align: right;">Page 149</p> <p>1 your report, and I've handed you Exhibit Number 13. That 2 is the picture that's on that page, correct? 3 A. Yes. 4 Q. Could you mark for me -- you said this 5 contains skeletal muscle in the explanted specimen. 6 Could you mark the skeletal muscle? 7 And what is skeletal muscle? 8 A. Skeletal muscle is different from smooth 9 muscle, because skeletal muscle is voluntary muscle. You 10 can move based on patient intention. And then smooth 11 muscle usually is not considered as a voluntary muscle. 12 It's different. Morphologically they also look 13 different. 14 Q. And where in the pelvis, female pelvis, 15 specifically in the path of the TVT-O device, do you find 16 skeletal muscle? 17 A. Should be in the obturator foramen area. 18 Q. Is that all? 19 A. I think so. Based on my understanding, this 20 is the area has definitive skeletal muscle. 21 Q. And is it true that you would find it also in 22 the hip adductor muscles that are beyond the obturator 23 foramen or distal to the obturator foramen, correct? 24 A. That's possible. 25 Q. Do you know whether Mrs. Edwards -- do you</p>

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<p>1 know if Mrs. Edwards had all of her mesh removed when she</p> <p>2 had her explant surgery?</p> <p>3 A. Based on my impression of reading the</p> <p>4 operative note, it seems it was completely removed.</p> <p>5 Q. Do you know if Ms. Huskey had all of her mesh</p> <p>6 removed?</p> <p>7 A. She had one portion seems -- based on</p> <p>8 operative records, one portion of the mesh left in the</p> <p>9 obturator foramen area, because it's quite deep.</p> <p>10 Q. So for Ms. Huskey, then, she would still have</p> <p>11 mesh remaining in the skeletal muscle of the hip adductor</p> <p>12 muscles and distal to the obturator foramen, correct?</p> <p>13 MR. SNELL: Foundation.</p> <p>14 A. No. Because I'm not sure. Nothing -- you</p> <p>15 know, this one -- whether assume this may be related to</p> <p>16 that area. And where is located, nobody knows. Whether</p> <p>17 it's closely associated to the skeletal muscle or not, we</p> <p>18 don't know, because I don't have the sample. Nobody has</p> <p>19 that. It's still within there.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. And you're not sure what muscles the TVT-O</p> <p>22 goes through getting -- when it's placed, correct?</p> <p>23 MR. SNELL: Misstates.</p> <p>24 A. Because the TVT-O is a transobturator</p> <p>25 procedure, then you have to pierce or pass through the</p>	<p>1 (By Ms. Thompson)</p> <p>2 Q. Do you recall ever getting a pathologic</p> <p>3 specimen other than mesh from the obturator foramen?</p> <p>4 A. No.</p> <p>5 Q. You don't have metas -- ovarian metastases in</p> <p>6 the obturator foramen, for example?</p> <p>7 A. Occasionally, yes, cancer can mess through</p> <p>8 that area. Then usually like, for instance, we have</p> <p>9 obturator lymph nodes. That's a common finding, yes.</p> <p>10 Q. So other than cancer spread to the obturator</p> <p>11 foramen or the lymph nodes in the area, are you aware of</p> <p>12 any other benign gynecological conditions that appear in</p> <p>13 the obturator foramen or beyond the obturator foramen in</p> <p>14 the hip adductor muscles?</p> <p>15 A. Occasionally we have so-called retroperitoneal</p> <p>16 tumors, and these tumors can be found in those area.</p> <p>17 Q. A retroperitoneal tumor is found in the hip</p> <p>18 adductor muscle?</p> <p>19 A. In the obturator foramen area, yes.</p> <p>20 Q. What type of tumors are those that you've</p> <p>21 seen, retroperitoneal tumor in the obturator foramen?</p> <p>22 A. That's more small cell carcinoma or something.</p> <p>23 It's maybe not related to this.</p> <p>24 Q. So we're still talking about cancer?</p> <p>25 A. Yes.</p>
Page 151	Page 153
<p>1 obturator membrane. That membrane partially has muscles</p> <p>2 there.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. Understand. But you also have to pass from</p> <p>5 the obturator foramen out the skin?</p> <p>6 A. Correct.</p> <p>7 Q. And that is the area -- well, if you do, do</p> <p>8 you know what anatomical structures are in that area?</p> <p>9 A. That area within the skin or adjacent area you</p> <p>10 may have some skeletal muscle fibers there, that's true.</p> <p>11 Q. Okay. But you don't know what muscles those</p> <p>12 are?</p> <p>13 A. I don't have the name for that.</p> <p>14 Q. Yeah. That's fine.</p> <p>15 Is the obturator space, if you recall this</p> <p>16 from your training as an OB-GYN or in your reading or</p> <p>17 viewing of pathology specimens or anything, is the</p> <p>18 obturator space an area where the typical gynecological</p> <p>19 surgeon operates?</p> <p>20 A. Absolutely.</p> <p>21 MR. SNELL: Outside the scope of his</p> <p>22 opinion. He's not here to talk about that.</p> <p>23 A. That's within the woman's pelvis, so should be</p> <p>24 within that area.</p> <p>25</p>	<p>1 Q. That's your specialty, so I understand that's</p> <p>2 what you like to talk about.</p> <p>3 MR. SNELL: Move to strike.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. I'm going to -- let's go back to the operative</p> <p>6 report on Ms. Edwards that I believe you have as</p> <p>7 Exhibit -- whatever it is.</p> <p>8 A. You mean this?</p> <p>9 Q. Yes.</p> <p>10 A. It's 11.</p> <p>11 Q. Just for efficiency sake, I'm going to direct</p> <p>12 you to the last paragraph on the second page that begins</p> <p>13 with the anterior wall. And in that it states --</p> <p>14 Dr. Galloway states that we identified the mesh. Do you</p> <p>15 see that?</p> <p>16 A. Yes.</p> <p>17 Q. And the mesh was divided in the midline and</p> <p>18 excised on both sides as far as possible into the vaginal</p> <p>19 apex.</p> <p>20 Wouldn't that suggest to you that the mesh</p> <p>21 was not removed in its entirety?</p> <p>22 A. I can't, you know, have that kind of</p> <p>23 impression. I think he did not say something left there.</p> <p>24 Q. Well, if it says it's excised as far as</p> <p>25 possible, doesn't that mean that it's not excised in</p>

<p style="text-align: right;">Page 154</p> <p>1 total?</p> <p>2 MR. SNELL: Form.</p> <p>3 A. If the surgeon is not sure whether it's</p> <p>4 completely excised, then he is the person in the position</p> <p>5 to make that statement. From what he described basically</p> <p>6 in usual situation should be removed.</p> <p>7 (By Ms. Thompson)</p> <p>8 Q. From your understanding of pelvic anatomy as a</p> <p>9 GYN pathologist, is it possible to access the obturator</p> <p>10 foramen and the hip adductor muscles through the vagina?</p> <p>11 A. It's difficult to, because it's quite deep.</p> <p>12 That's why they have a special trocar to go through that</p> <p>13 rather than -- yes. It's quite deep.</p> <p>14 Q. During insertion there's a special trocar?</p> <p>15 A. Correct.</p> <p>16 Q. Unfortunately there's not a special trocar for</p> <p>17 removal, right?</p> <p>18 A. That's true.</p> <p>19 MR. SNELL: Form.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. And, in fact, transobturator slings typically</p> <p>22 have to be removed, if you are trying to remove the</p> <p>23 entire thing, through a groin incision; is that not</p> <p>24 correct?</p> <p>25 MR. SNELL: Outside the scope.</p>	<p style="text-align: right;">Page 156</p> <p>1 MS. THOMPSON: Sorry.</p> <p>2 (By Ms. Thompson)</p> <p>3 Q. So they're synonymous. If you or I have used</p> <p>4 skeletal or striated, we mean the same things?</p> <p>5 A. Right.</p> <p>6 Q. And fortunately they both start with S so --</p> <p>7 A. I used SK.</p> <p>8 Q. That striated muscle is within the pores of</p> <p>9 the mesh; is that correct?</p> <p>10 A. I'm not sure. This is -- because several</p> <p>11 millimeter away from the mesh fiber spaces. All right?</p> <p>12 As you can see, in this power I'm not able to include any</p> <p>13 mesh. That means already several millimeter away.</p> <p>14 Q. You would agree with me, though, that the</p> <p>15 striated muscle is within the fibrosis, correct?</p> <p>16 A. Within the soft tissue adjacent to the mesh</p> <p>17 fiber. That would be more accurate statement.</p> <p>18 Q. But this is fibrosis, wouldn't you agree?</p> <p>19 A. No. This is sort of connective tissue,</p> <p>20 because you have so many soft tissues, including vessels</p> <p>21 and fibroblasts and skeletal muscle. So it's adjacent.</p> <p>22 It's like I think if you can refer back to</p> <p>23 your gross picture for the specimen, this one, you see</p> <p>24 these? You can see mesh, right? See that mesh? Then</p> <p>25 adjacent to the mesh you see these area. They are all</p>
<p style="text-align: right;">Page 155</p> <p>1 A. That's really not within my specialty,</p> <p>2 surgical procedures. So I would like to defer to the</p> <p>3 surgeons to answer that.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. But pelvic anatomy is in your specialty area,</p> <p>6 correct?</p> <p>7 A. Pelvic anatomy in general, yes.</p> <p>8 Q. Okay. But knowing whether or not you can get</p> <p>9 mesh that's integrated to the tissue out from the hip</p> <p>10 adductor muscles through the vagina is not something that</p> <p>11 you would be able to know?</p> <p>12 A. Correct. Because that's surgical procedure.</p> <p>13 Q. All right. On page 17 -- oh, we're still on</p> <p>14 17. Sorry. And you marked the striated muscle. And I</p> <p>15 believe you said that that is in the explanted mesh</p> <p>16 specimen. Is that in the pores?</p> <p>17 MR. SNELL: Form.</p> <p>18 Did you say striated muscle? I think you</p> <p>19 said you marked the striated muscle? What did you mean</p> <p>20 by that?</p> <p>21 MS. THOMPSON: He marked it on the</p> <p>22 exhibit.</p> <p>23 THE WITNESS: Striated is equivalent to</p> <p>24 skeletal muscle. Striated muscle is a more professional</p> <p>25 pathological term to describe skeletal muscle.</p>	<p style="text-align: right;">Page 157</p> <p>1 soft tissues. So this is several millimeters away.</p> <p>2 I can't be sure, but based on the picture</p> <p>3 I took, most likely those skeletal muscles are several</p> <p>4 millimeters away from the mesh. That's why I say in</p> <p>5 adjacent soft tissue. Then that indicating this kind of</p> <p>6 muscular fibers found in the slide could also be related</p> <p>7 to the surgery, because the surgeon cannot just cut the</p> <p>8 mesh alone. He has to include some several millimeter of</p> <p>9 the soft tissue closely associated with the mesh. Then</p> <p>10 he cut.</p> <p>11 Q. So it would be fair to say, though, that the</p> <p>12 skeletal muscle is either within the pores of the mesh or</p> <p>13 it's very close to the mesh, correct?</p> <p>14 MR. SNELL: Form. Misstates.</p> <p>15 He's already told you where it is. You</p> <p>16 keep trying to get him to say something. He said three</p> <p>17 times it's adjacent to it.</p> <p>18 MS. THOMPSON: I don't believe that's what</p> <p>19 he said. He said he couldn't tell whether it was in the</p> <p>20 mesh or adjacent to it.</p> <p>21 MR. SNELL: No. He said it was adjacent.</p> <p>22 A. I said, yes, the skeletal muscle found is</p> <p>23 adjacent to the mesh fiber. That's why I want to show</p> <p>24 you this gross picture, because this picture is basically</p> <p>25 one X. It's a real specimen. Then these area, bluish</p>

<p style="text-align: right;">Page 158</p> <p>1 area, represent a mesh. Then adjacent to these mesh, we</p> <p>2 see lots of soft tissues.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. So you have tissue within the mesh, and you</p> <p>5 have tissue adjacent to the mesh, right?</p> <p>6 A. Right. Within the mesh I'm able to see these</p> <p>7 adjacent to -- immediately adjacent to the skeletal</p> <p>8 muscle, then I will see mesh fiber spaces.</p> <p>9 Q. So -- sorry.</p> <p>10 A. For instance --</p> <p>11 MR. SNELL: Do you want your photos?</p> <p>12 A. Yeah, here, like this. You see, these like</p> <p>13 lots of spaces, like these are spaces, these are mesh</p> <p>14 fiber spaces, right?</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. Correct.</p> <p>17 A. And then if between these two mesh fiber</p> <p>18 spaces you see these fibrotic -- mild degree of fibrosis</p> <p>19 or soft tissue there, then that's within the mesh fiber,</p> <p>20 mesh pores. But this one --</p> <p>21 MR. FABRY: Just for the record, Doctor,</p> <p>22 you're referring to page 14 of your report, Figure 5, in</p> <p>23 your last testimony?</p> <p>24 THE WITNESS: Correct.</p> <p>25 A. And then these skeletal muscles, when I take a</p>	<p style="text-align: right;">Page 160</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Okay. Could muscle -- striated muscle</p> <p>3 adjacent to mesh cause pain?</p> <p>4 A. In a very, very broad sense, maybe there is</p> <p>5 association. But these muscle fibers, also you can</p> <p>6 notice these are so-called isolated foci of these</p> <p>7 muscular cells. All right? It's different from the</p> <p>8 muscle like our arm muscles. When we move our arm, we</p> <p>9 have a bunch of these muscle fibers. It's very obvious.</p> <p>10 When we take a section, then we show -- we will see this.</p> <p>11 Under the microscope, we will see pure muscle fibers.</p> <p>12 And here is a few skeletal muscle cells.</p> <p>13 It's quite gigantic cells, one big one, you see this one,</p> <p>14 one dot basically is one cell or part of a single cell.</p> <p>15 Q. But you would assume, would you not, that</p> <p>16 those muscle cells are attached to a muscle, correct?</p> <p>17 MR. SNELL: Form.</p> <p>18 A. No. Because these isolated muscle cells may</p> <p>19 possibly may be related to procedure, as I said, because</p> <p>20 we have transobturator procedure for the TVT-O procedure,</p> <p>21 right? Then this tape is -- have to pass through</p> <p>22 obturator foramen. Therefore, there is a possibility</p> <p>23 these small amount of muscle cells being attached or</p> <p>24 being pulled by the procedure, by the tape.</p> <p>25</p>
<p style="text-align: right;">Page 159</p> <p>1 photograph, actual mesh fibers are here. I'm not able to</p> <p>2 include it within the same field, because of the</p> <p>3 limitation of the microscope.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. So you can say with certainty that that</p> <p>6 skeletal muscle is not within the pores of the mesh?</p> <p>7 A. Right. I'm pretty sure it's not within the</p> <p>8 mesh pore spaces.</p> <p>9 Q. What is desmin staining?</p> <p>10 A. Okay. Desmin staining means usually this can</p> <p>11 positively identify skeletal muscle.</p> <p>12 Q. And you said figure not shown. Did you do</p> <p>13 desmin staining?</p> <p>14 A. I did not do desmin staining, but</p> <p>15 Dr. Iakovlev, he did it. I read it and reviewed it.</p> <p>16 Q. Any reason why you did not show that figure?</p> <p>17 A. Because I don't think there's a reason to show</p> <p>18 that. He has one of the pictures showing some skeletal</p> <p>19 muscles a little bit closer to -- maybe to the mesh</p> <p>20 fiber. That's true. I remember that.</p> <p>21 Q. But you didn't want to show that one in your</p> <p>22 report?</p> <p>23 MR. SNELL: Form. Asked and answered.</p> <p>24 A. Because I see no point there.</p> <p>25</p>	<p style="text-align: right;">Page 161</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Okay. So you're telling me that the</p> <p>3 possibility is that those muscle cells were pulled in by</p> <p>4 the tape, by the mesh tape, and they're isolated muscle</p> <p>5 cells in the fibrotic? But they're not in the mesh.</p> <p>6 They're just --</p> <p>7 A. Adjacent to the soft tissue.</p> <p>8 Q. -- adjacent to the mesh. So how does the mesh</p> <p>9 pull it in but it's not in the mesh?</p> <p>10 MR. SNELL: Form.</p> <p>11 Go ahead.</p> <p>12 A. Because that's the surgical procedure. If you</p> <p>13 have foramen like this, then you have a tape went</p> <p>14 through, then if you have some muscle fibers already</p> <p>15 muscle attached to these area, then you have to go</p> <p>16 through, right? Then you have to -- just like a</p> <p>17 contamination.</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. And you -- but you're not of the opinion that</p> <p>20 that would hurt to have those muscles pulled in like that</p> <p>21 and left?</p> <p>22 A. Because that's within the -- a small amount of</p> <p>23 muscle cells isolated there. They do not connect.</p> <p>24 Nobody can be sure they are connecting to the main muscle</p> <p>25 or not. Because based on these pictures, it's just</p>

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1 there. That's it.

2 Q. And muscle cells pulled in in that way

3 could -- do they have a blood supply, isolated muscle

4 cells?

5 A. Here they are adjacent to the blood vessels.

6 See that? These are all blood vessels.

7 Q. So your theory, then, is that those blood

8 vessels there are supplying an isolated group of muscle

9 cells that were pulled in with the tape seven years

10 previously?

11 A. When you have a small amount of muscle cells,

12 you do not need direct vascular supply to keep them

13 alive. Okay?

14 Q. Does muscle hurt when it's penetrated by a

15 foreign object?

16 MR. SNELL: Form.

17 A. When the patient in surgery, she will feel

18 nothing, because that's in the anesthesia condition.

19 (By Ms. Thompson)

20 Q. We will agree on that one. I'm talking about

21 afterwards. Does it hurt to put a foreign object through

22 muscle?

23 MR. SNELL: Same objection. Form.

24 A. Because that's the procedure already done.

25 All right. When you pass through, then if without

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1 anesthesia, possible, sure, will feel hurt. That's why

2 you need anesthesia.

3 (By Ms. Thompson)

4 Q. How about afterwards?

5 A. Afterwards, if you don't do anything, I don't

6 think there is anything particular painful feeling.

7 Q. Are you aware of pain associated with

8 transobturator slings, chronic pain?

9 A. Chronic pain also again is a very vague or

10 broad term to cover many, many specific pain, such as

11 vaginal pain, groin pain, or these pelvic pain. And then

12 overall people say chronic pain or long-term pain and

13 whether it's specifically related to that. But based on

14 report, my impression overall pain rate is also low.

15 MS. THOMPSON: I'm going to mark

16 Exhibit 14.

17 (Marked for Identification:

18 Deposition Exhibit No. 14)

19 (By Ms. Thompson)

20 Q. You can go ahead and take a minute to look at

21 that and let me know if you've seen this before.

22 A. I never seen this before.

23 Q. Go ahead and take -- do you know French?

24 A. No.

25 Q. It does have a translation, so take a minute

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1 to review that.

2 Are you ready, Dr. Zheng?

3 A. That was -- the meeting happened like 10 years

4 ago?

5 Q. Yes. And I'll give you a little context.

6 What is the date on this document?

7 A. This says March 29, 2004.

8 Q. And do you know when the TVT-O was cleared for

9 marketing in the United States?

10 A. I'm not sure for that.

11 Q. I'm going to tell you it's December of 2003,

12 if that's okay. We'll assume it is.

13 Reading in the first paragraph where it

14 says, You will find hereafter, could you read me that

15 says what this meeting was about? You will find

16 hereafter...

17 A. I'm not sure I understand what's the main

18 purpose for this meeting.

19 Q. Okay. Well, it says it's a confidential

20 meeting held in Miami and relates to possible

21 modifications of TVT-O. Is that what it says?

22 A. Correct.

23 Q. And so within a few months of marketing, they

24 are looking at possibly modifying the TVT-O. Would you

25 agree?

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1 MR. SNELL: Foundation.

2 Go ahead.

3 A. If that's -- the date is correct, yes.

4 (By Ms. Thompson)

5 Q. And they suggest several modifications,

6 possible modifications. The first, under number one, is

7 removal of the segment of the tape that passes through

8 the adductor muscles, possibly causing postoperative

9 pain. Do you see that?

10 A. With a question mark.

11 Q. With a question mark?

12 A. Yes.

13 Q. So you would assume from this that somebody

14 was aware that the tape passing through the adductor

15 muscles could possibly be causing postoperative pain,

16 correct?

17 MR. SNELL: Form, foundation.

18 A. Somebody may raise that concern, that's true.

19 (By Ms. Thompson)

20 Q. And the second possible modification within a

21 few months after marketing and to address pain associated

22 with the TVT-O was that you could decrease the diameter

23 of the device traversing the adductor muscles, in

24 parentheses, other possible cause of pain, question mark,

25 correct?

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<p>1 MR. SNELL: Same objection.</p> <p>2 Go ahead.</p> <p>3 A. Yeah. I think those are mainly surgical</p> <p>4 procedure related. I don't know if my opinion -- or I'm</p> <p>5 the person in this position to make those comments, you</p> <p>6 know, when I'm reading through -- partially through this</p> <p>7 document.</p> <p>8 (Marked for Identification:</p> <p>9 Deposition Exhibit No. 15)</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Okay. And I'll also give you an article.</p> <p>12 Exhibit Number 15 is a randomized trial. And in the</p> <p>13 results, this article states that more women complained</p> <p>14 of leg pain after receiving a tension-free vaginal</p> <p>15 tape-obturator, 26.4 percent versus 1.7 percent.</p> <p>16 Do you see that? Is that what it says?</p> <p>17 A. Yes.</p> <p>18 Q. 26.4 percent would not be considered rare,</p> <p>19 would it?</p> <p>20 A. I think I have to read the whole article to</p> <p>21 kind of study and decide in which condition to understand</p> <p>22 better those results or the findings or their</p> <p>23 conclusions.</p> <p>24 Q. And you can read the article, but is there any</p> <p>25 situation where 26.4 percent, over a quarter of women</p>	<p>1 A. Compared to other mesh I have seen, yes, they</p> <p>2 look very much similar.</p> <p>3 Q. Okay. And the majority of the specimens in</p> <p>4 Dr. Iakovlev's report are specifically identified as</p> <p>5 either Ms. Edwards' or TVT-O explants, correct?</p> <p>6 MR. SNELL: Foundation on that.</p> <p>7 A. I'm not sure. Only six explanted mesh they</p> <p>8 represented TVT mesh specimen. And the remaining he did</p> <p>9 not say where they are coming from, what kind of brand.</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Well, according to Dr. Iakovlev's</p> <p>12 calculations, 72 percent of the pictures are TVT-O</p> <p>13 explants. Would you argue with that if that's what he</p> <p>14 said?</p> <p>15 MR. SNELL: Foundation and form. I don't</p> <p>16 know when he said that.</p> <p>17 A. Do you also recognize that he said only six</p> <p>18 explanted TVT mesh -- actually only six explanted TVT was</p> <p>19 the mesh was from TVT specimen. So that's why those</p> <p>20 figures were conflicting each other from his own report</p> <p>21 if the number you just give to me was true.</p> <p>22 (By Ms. Thompson)</p> <p>23 Q. And I think that's the photographs in the</p> <p>24 report. But it is what it is.</p> <p>25 In number two, when you say Dr. Iakovlev's</p>
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<p>1 with any complication, that you would consider that rare?</p> <p>2 A. No. Twenty-five -- around 25 percent findings</p> <p>3 is reasonably significant.</p> <p>4 Q. And on page 1354, the last paragraph, these</p> <p>5 particular authors actually stopped their study early</p> <p>6 because of the growing evidence of equal efficacy but a</p> <p>7 significantly increased incidence of postoperative leg</p> <p>8 pain after transobturator insertion, correct? That's</p> <p>9 what the article says?</p> <p>10 A. That's what the article says.</p> <p>11 Q. You state -- I'm now on page 17, the bottom</p> <p>12 portion starting with general opinion.</p> <p>13 A. Yes.</p> <p>14 Q. You state that Dr. Iakovlev presented many</p> <p>15 pathological pictures, only some of which were derived</p> <p>16 from Ms. Edwards, and attempts to extrapolate from these</p> <p>17 other explanted meshes to support his opinion that all</p> <p>18 vaginal meshes, not brand specific, are linked to</p> <p>19 clinical complications.</p> <p>20 We're going to leave off the due to the</p> <p>21 defective manufacturing or design. I don't believe he</p> <p>22 said that.</p> <p>23 You, I think, yourself have stated that</p> <p>24 Ms. Edwards' pathology and findings are typical of other</p> <p>25 mesh that you've seen, correct?</p>	<p>1 cohort is uncontrolled and is not randomly selected, what</p> <p>2 do you mean by that?</p> <p>3 A. Okay. Because, based on my understanding, his</p> <p>4 130 mesh specimens were collected without any like</p> <p>5 experimental design. It's not experiments, first of all.</p> <p>6 It's a collection of the specimen from those patients or</p> <p>7 from whatever the law office give to him. Right? That's</p> <p>8 why -- that's the nature for these specimens. That's</p> <p>9 what I mean.</p> <p>10 Q. How do you randomize the collection of mesh</p> <p>11 explants?</p> <p>12 A. Right. Because if you want to make some</p> <p>13 conclusions basically, you have to do some experimental</p> <p>14 design, then generate some data. These data will be more</p> <p>15 useful or scientifically sound rather than make some</p> <p>16 collections and make some statements.</p> <p>17 Because these all -- whatever, as we</p> <p>18 discussed earlier, all these specimens came out. They</p> <p>19 have their own reasons. Right? They can have medical</p> <p>20 reasons or can have legal reasons. So they are true</p> <p>21 complicated. Without each specified reasons, how can you</p> <p>22 analyze as a collection?</p> <p>23 Says, okay, from 130 specimens I analyzed</p> <p>24 and I found this and that. And, therefore, based on</p> <p>25 these findings, I can conclude, you know, the remaining</p>

<p style="text-align: right;">Page 170</p> <p>1 specimens they will be the same thing. No. That's --</p> <p>2 you see the scientific papers, you are quoting lots of</p> <p>3 papers and I'm quoting lots of papers. All these papers</p> <p>4 they publish they have a specific method, right? Then</p> <p>5 all these methods will give you -- give you a reason.</p> <p>6 That's why including case numbers and the study design,</p> <p>7 each of these.</p> <p>8 Q. But you will agree with me that you can't</p> <p>9 randomize and control an observational study of mesh</p> <p>10 explants, can you?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. But if you have collections, then basically</p> <p>13 these are not studied. Therefore, you cannot use those</p> <p>14 findings to generalize the concept.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. What's an observational study?</p> <p>17 A. What's -- there is -- what do you mean what's</p> <p>18 observational study?</p> <p>19 Q. I'm asking you the question. Does that mean</p> <p>20 anything to you?</p> <p>21 A. Observational, for instance, you have case</p> <p>22 report. You can report a case. But case report value,</p> <p>23 scientific value compared to randomized study or clinical</p> <p>24 trial, they have totally different value. Okay?</p> <p>25 So then from that point of view,</p>	<p style="text-align: right;">Page 172</p> <p>1 A. And then also for those evaluations for</p> <p>2 specific like Edwards specimens, then based on my</p> <p>3 experience in the past years as a GYN pathologist.</p> <p>4 Right. Also experience to evaluate the mesh specimens in</p> <p>5 the past three years.</p> <p>6 Q. So your experience is not useless but</p> <p>7 Dr. Iakovlev's is?</p> <p>8 MR. SNELL: Form. Misstates.</p> <p>9 A. I don't say that. I don't know how to respond</p> <p>10 to this kind of -- you know, your question for that.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. Okay. We'll move on.</p> <p>13 What do you mean by the statement TVT</p> <p>14 including TVT-O? Is TVT-O a TVT, in your opinion?</p> <p>15 A. Yes. The mesh from mesh point of view, they</p> <p>16 are the same.</p> <p>17 Q. From mesh point of view, but you would agree</p> <p>18 that not from a procedure point of view?</p> <p>19 A. Yeah. Procedure is different.</p> <p>20 Q. Can you direct me to the literature -- and I'm</p> <p>21 looking now at page 18, the first paragraph. Can you</p> <p>22 point me to the literature that recognizes TVT-O as the</p> <p>23 gold standard and standard of care?</p> <p>24 A. I think we have some professional society</p> <p>25 position statement. Those documents they state very</p>
<p style="text-align: right;">Page 171</p> <p>1 Dr. Iakovlev's collection of these 130 samples, even he</p> <p>2 did not report any of them to the public literature, try</p> <p>3 to make his opinion to be accepted by the general readers</p> <p>4 or audience or to contribute to the scientific community.</p> <p>5 Q. And are you suggesting that, because of that,</p> <p>6 his opinions are unreliable?</p> <p>7 A. Basically these are not peer reviewed, not</p> <p>8 under any kind of validation process. Therefore, these</p> <p>9 opinions they're useless.</p> <p>10 Q. And are your opinions peer reviewed?</p> <p>11 A. My opinion is not peer reviewed. But based on</p> <p>12 the findings, those are just -- because specifically to</p> <p>13 reply to what he stated. That's my opinion. And then</p> <p>14 also my general opinion is based on the literature</p> <p>15 published. Right? You understand?</p> <p>16 Q. What of your general opinions are based on the</p> <p>17 literature published?</p> <p>18 A. Within this report, like previous one we</p> <p>19 discussed biocompatibility, tissue integration, those are</p> <p>20 the general opinions, right?</p> <p>21 Q. Okay. We'll get to some more of those later.</p> <p>22 A. And then -- right.</p> <p>23 Q. But you're saying that the opinions in your</p> <p>24 report are based on the literature published, and for</p> <p>25 that reason are not useless as Dr. Iakovlev's --</p>	<p style="text-align: right;">Page 173</p> <p>1 clearly saying TVT and TVT-O are the gold standard.</p> <p>2 MR. SNELL: Do you want your materials?</p> <p>3 You can look through them.</p> <p>4 (By Ms. Thompson)</p> <p>5 Q. I'm specifically talking about TVT-O as the</p> <p>6 gold standard. And I will give you some time to look for</p> <p>7 the support for that statement.</p> <p>8 We can -- shall we take a break?</p> <p>9 MR. SNELL: It'll only take a minute. The</p> <p>10 professional statements, he's got a whole binder here.</p> <p>11 MS. FITZPATRICK: If you want to take a</p> <p>12 break, Margaret, you can.</p> <p>13 MS. THOMPSON: Let's take a break.</p> <p>14 THE VIDEOGRAPHER: Off the record 4:28.</p> <p>15 (Recess taken.)</p> <p>16 (Ms. Fitzpatrick no longer present.)</p> <p>17 THE VIDEOGRAPHER: On the record 4:44.</p> <p>18 (By Ms. Thompson)</p> <p>19 Q. When we went off the record, Dr. Zheng, I</p> <p>20 believe you were going to look for statements from</p> <p>21 professional societies identifying the TVT-O as the gold</p> <p>22 standard for treatment of stress incontinence. Have you</p> <p>23 found something?</p> <p>24 A. Yes. I think because in the short time period</p> <p>25 I had, I can show you one article which is published in</p>

<p style="text-align: right;">Page 174</p> <p>1 Nature as a review article by Ashley Cox, C-O-X, okay, 2 from University of Toronto. This is also very good 3 article because it's published in Nature. That's Nature 4 urology section. It's last year.</p> <p>5 I give you the last sentence of the 6 abstract. It says, Based on the literature, a new gold 7 standard of first line surgical treatment for women with 8 SUI, surgical urinary incontinence or stress urinary 9 incontinence, is the synthetic mid urethral sling 10 inserted through a retropubic or transobturator approach.</p> <p>11 So here transobturator approach represents 12 TVT-O. You can have this.</p> <p>13 Q. Well, I asked for something that actually 14 identified the TVT-O as the gold standard.</p> <p>15 A. Yeah. This is basically -- clearly says this 16 is a TVT-O, right?</p> <p>17 Q. Well, I beg to differ. It says transobturator 18 slings, and as you know, they're different inside to out, 19 outside to in, different materials, different companies.</p> <p>20 A. Well, if you read through, also summarize 21 inside to out, outside to in. It also says TVT-O.</p> <p>22 Q. So I'll just read what you've given me. It 23 says that the gold standard first line surgical treatment 24 is the synthetic mid urethral sling inserted through a 25 retropubic or transobturator approach, but does not state</p>	<p style="text-align: right;">Page 176</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. And is that the one that you found; that you 3 were not able to find any statements from professional 4 organizations?</p> <p>5 A. I think we have position statements. Just, 6 you know, this is a lot. If you go through, definitely 7 it's there. You know, we don't have enough time within 8 this time finding specific word or letter-by-letter match 9 statement. But it's there.</p> <p>10 MS. THOMPSON: Okay.</p> <p>11 MR. SNELL: For the record, you were just 12 pointing to one of the binders you brought to your 13 deposition today. It's titled Position Statements with 14 18 different position statements?</p> <p>15 THE WITNESS: Yes.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. Let's go to page 18 of your report. The first 18 one that states -- and these are now, I guess, criticisms 19 on page 18 and 19, 1 through 4, of Dr. Iakovlev's 20 opinion; is that correct?</p> <p>21 A. Correct.</p> <p>22 Q. Number one, you state that he relied too 23 heavily on S100 staining. But I believe you've said that 24 a competent pathologist doesn't need any special staining 25 to identify nerves, so it seems to me that that opinion</p>
<p style="text-align: right;">Page 175</p> <p>1 what I actually was looking for, that the TVT-O is the 2 gold standard, and I believe that's what your report 3 said.</p> <p>4 MR. SNELL: Form. Misstates.</p> <p>5 I think he pointed you to TVT-O inside the 6 article as well.</p> <p>7 A. Because summary usually people use different 8 word to describe same thing. But you are asking for 9 specific word, single letter-by-letter match. That's the 10 difference.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. Yeah. I was specifically looking for the 13 TVT-O identified as the gold standard. That's true.</p> <p>14 A. TVT-O, yes, has been mentioned. Approach is 15 included within their review scope.</p> <p>16 Q. Not to be argumentative, but I believe it's 17 different from articles with TVT-O included in a review 18 than it is to say that specific TVT-O is the gold 19 standard, but we'll leave it at that.</p> <p>20 A. Right. Because --</p> <p>21 Q. No, no. There's no question on the table.</p> <p>22 MR. SNELL: That's not a question. It 23 doesn't matter what she thinks. It's your opinions that 24 are important. 25</p>	<p style="text-align: right;">Page 177</p> <p>1 is irrelevant. Do you agree?</p> <p>2 MR. SNELL: Form.</p> <p>3 A. No. Because he made a statement -- lots of 4 statements based on S100 staining. Then here what my 5 point is, if it's real good nerve fibers, they are easily 6 identifiable, number one.</p> <p>7 Number two is S100 staining is nonspecific 8 for nerve fiber only. It cannot only stain nerve fiber, 9 also can stain non-nerve fibers. That's the second 10 statement.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. But why do you need specificity if you can 13 look at the structure and tell whether it's a nerve or 14 not?</p> <p>15 A. That's why, you know, he used that. He tried 16 to make these broad colors for these nonprofessionals 17 maybe will be happy for, saying, oh, now I can see 18 because it's highlighted.</p> <p>19 Q. Do you have a copy of Dr. Iakovlev's report 20 with you?</p> <p>21 A. Yes, somewhere.</p> <p>22 No. I did not bring. But I think 23 somewhere in...</p> <p>24 Q. Let's go ahead and find that since you relied 25 on that, his report.</p>

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<p>1 A. But I have one of the pictures, one of the</p> <p>2 pictures he took from his basically similar field,</p> <p>3 like --</p> <p>4 Q. Yeah. Let's just go ahead and get the report.</p> <p>5 A. Okay. You want to get his report, right?</p> <p>6 Q. Yes.</p> <p>7 A. That's fine.</p> <p>8 THE WITNESS: Do we have his report?</p> <p>9 MR. SNELL: Do you have a copy for him?</p> <p>10 MS. THOMPSON: No, I don't. He brought it</p> <p>11 with his reliance materials, I believe.</p> <p>12 MR. SNELL: Oh, you have it there?</p> <p>13 MR. SNOWDEN: This is my copy.</p> <p>14 MR. SNELL: Is it the color copy?</p> <p>15 MR. SNOWDEN: For the record, if there are</p> <p>16 any stray markings on that, they're mine.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. So would you identify for me the portions of</p> <p>19 Dr. Iakovlev's report that indicated to you that he</p> <p>20 relied too heavily on S100 staining?</p> <p>21 A. Because in his report many places described</p> <p>22 S100 staining, number one. He also even described based</p> <p>23 on S100 staining he made comments, says the nerve --</p> <p>24 so-called nerve densities is about 1.37 per field, which</p> <p>25 field is under 200 magnifications, right?</p>	<p>1 Q. Can you give me the page, please?</p> <p>2 A. Page 18, Figure 3a says superficial nerve</p> <p>3 position.</p> <p>4 Q. Okay.</p> <p>5 A. Did you see that?</p> <p>6 Q. So are you suggesting that these are not</p> <p>7 nerves?</p> <p>8 A. Let me explain to you. So you see --</p> <p>9 Q. I'm asking you a question. Do you believe</p> <p>10 that these are not nerves?</p> <p>11 A. I say these are nerve-like element. You can</p> <p>12 see my report.</p> <p>13 Q. What do you mean by nerve-like element?</p> <p>14 A. Because this could be nerve, could not be</p> <p>15 nerve basically. Okay?</p> <p>16 Q. So you can't tell whether these are nerves or</p> <p>17 not?</p> <p>18 A. Because under regular microscope, these not</p> <p>19 like truly identifiable nerve fibers. I can show you a</p> <p>20 picture.</p> <p>21 Q. Did you take the slide and put it on high</p> <p>22 power and see if you could tell whether they were nerves</p> <p>23 or not?</p> <p>24 A. Yes, I put on high power.</p> <p>25 Q. And you could not tell under high power</p>
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<p>1 Q. And that was per high-powered field, correct?</p> <p>2 A. That's intermediate. Basically it's 20 by 10.</p> <p>3 It's 200. It's intermediate.</p> <p>4 Q. So you're suggesting that Dr. Iakovlev made</p> <p>5 those determinations based on brown spots and not on</p> <p>6 nerve identification?</p> <p>7 A. Right. Because this is number one. Number</p> <p>8 two is whatever he claim as a nerve based on S100</p> <p>9 staining results.</p> <p>10 Q. But you've stated that a competent pathologist</p> <p>11 identifies nerves based on the morphology not by the</p> <p>12 stain anyway, correct?</p> <p>13 MR. SNELL: Form. Misstates.</p> <p>14 Go ahead.</p> <p>15 A. Number one I say if it's well-formed nerve,</p> <p>16 you don't need staining to recognize, number one.</p> <p>17 Number two, S100, yes, can stain these</p> <p>18 nerve fibers, but meanwhile this is not specific for</p> <p>19 nerve fibers. Also stains for nonnerve elements.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. Would you show me one of the pictures or the</p> <p>22 text from Dr. Iakovlev's report that makes you think that</p> <p>23 he's relying on brown spots rather than the</p> <p>24 identification of nerves?</p> <p>25 A. Okay. Here he has --</p>	<p>1 whether these were nerves or not?</p> <p>2 A. Yeah, for those particular field, all right,</p> <p>3 he took the picture. Under H&E slide I'm not able to</p> <p>4 tell those are true nerve.</p> <p>5 Q. I'm asking you, for this picture on page 18</p> <p>6 that you say that you cannot tell whether those are</p> <p>7 nerves or not, did you take that portion of the slide,</p> <p>8 look at it under high-powered field, and make a</p> <p>9 determination whether those were morphologically nerves</p> <p>10 or not?</p> <p>11 A. I turn on high power for those particular</p> <p>12 field from H&E slide. But you have to understand, H&E</p> <p>13 slide, although they look like parallel levels, but it's</p> <p>14 not identical to those S100 staining slide. I don't know</p> <p>15 if you understand that or not.</p> <p>16 Because one slide you make H&E, and the</p> <p>17 deep levels he used for S100 staining. So, therefore, I</p> <p>18 examined H&E slide in the corresponding area for him to</p> <p>19 stain with S100. I'm not able to identify the nerve</p> <p>20 under regular light microscope.</p> <p>21 Q. I'm just showing you this on my computer,</p> <p>22 because it's, I think, a clearer picture than what we</p> <p>23 have printed.</p> <p>24 Are you telling me here today -- this is</p> <p>25 the same photo that you're looking at --</p>

<p style="text-align: right;">Page 182</p> <p>1 A. Correct.</p> <p>2 Q. -- that you cannot tell whether those are</p> <p>3 nerves or not?</p> <p>4 A. Those --</p> <p>5 Q. Yes or no, can you tell whether those are</p> <p>6 nerves or not?</p> <p>7 A. I cannot be sure.</p> <p>8 Q. You cannot be sure. Okay. That's what I need</p> <p>9 to hear.</p> <p>10 A. That's number one. Then --</p> <p>11 Q. Okay. That's all.</p> <p>12 MR. SNELL: Well, I think he's allowed to</p> <p>13 explain his answer. The judge has ruled you can give a</p> <p>14 yes or no and then explain.</p> <p>15 MS. THOMPSON: It's funny how you told us</p> <p>16 last time that the judge told us he has to answer yes or</p> <p>17 no.</p> <p>18 MR. SNELL: That's what he did, he just</p> <p>19 answered. But then they're permitted to explain. Your</p> <p>20 problem was Iakovlev gave me four sentences of nonsense</p> <p>21 and then answered my question.</p> <p>22 MS. THOMPSON: I object to that and</p> <p>23 strike.</p> <p>24 MR. FABRY: I'm going to object to the</p> <p>25 commentary. If he wants to explain, I think that's okay.</p>	<p style="text-align: right;">Page 184</p> <p>1 MR. SNELL: Form.</p> <p>2 A. No. Because all his statement he said all</p> <p>3 these brown stained area represent either nerve twigs or</p> <p>4 nerve branches.</p> <p>5 (By Ms. Thompson)</p> <p>6 Q. Where does he say all the brown stained areas</p> <p>7 represent nerve twigs or nerve branches? Would you find</p> <p>8 that for me in his report?</p> <p>9 A. I think we are wasting a lot of time to find</p> <p>10 these specific --</p> <p>11 Q. I can spend my time any way I want to,</p> <p>12 Dr. Zheng.</p> <p>13 A. Okay.</p> <p>14 Q. I want you to find where he say that all the</p> <p>15 brown spots are either nerve twigs or branches.</p> <p>16 A. Okay. He basically state all these brown</p> <p>17 stainings represent a nerve.</p> <p>18 Q. Where are you?</p> <p>19 A. Here, let's, for instance, go to Figure 1a,</p> <p>20 nerve ingrowth. It says page 12. Explanted TVT-O sling</p> <p>21 specimen of Mrs. Edwards, immunostaining against S100</p> <p>22 protein to identify peripheral nerve. Do you see that?</p> <p>23 Q. Yes.</p> <p>24 A. Okay. Nerves brown, all other tissue blue,</p> <p>25 mesh filaments transparent, right, all other tissue blue.</p>
<p style="text-align: right;">Page 183</p> <p>1 MS. THOMPSON: Yeah, he can explain.</p> <p>2 MR. SNELL: Were you finished, Doctor?</p> <p>3 A. Okay. So let me give you additional</p> <p>4 explanation why I say S100 is nonspecific. Okay? From</p> <p>5 his picture, the same picture, you can look at your</p> <p>6 screen, you see the brown spots, okay, are stainings.</p> <p>7 Not only present in the submucosal area, it's also</p> <p>8 present within the squamous mucosa. Did you see that?</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. Did Dr. Iakovlev make any comment on the brown</p> <p>11 spots in the mucosa?</p> <p>12 A. He did not, but --</p> <p>13 Q. He only made a comment, correct, on the nerve</p> <p>14 branches between the mesh and the mucosa, correct?</p> <p>15 A. He says superficial position. Okay?</p> <p>16 Q. Well, he says the nerves are running between</p> <p>17 the hard mesh and the mucosa, correct?</p> <p>18 A. Right. But the picture he take -- he took</p> <p>19 here clearly show brown staining in the mucosa as well as</p> <p>20 submucosa area. Right?</p> <p>21 Q. And the brown staining on low-powered field</p> <p>22 allows you to save time, go into the area where the brown</p> <p>23 staining is, and then morphologically, which is all what</p> <p>24 pathologists do, identify whether they're nerves or not,</p> <p>25 correct?</p>	<p style="text-align: right;">Page 185</p> <p>1 So everything brown means nerve. Right? Do I understand</p> <p>2 correctly?</p> <p>3 Q. He says the nerves are brown? Where does</p> <p>4 he --</p> <p>5 A. Nerves are brown, yes. Nerves are brown.</p> <p>6 Then what else? Then here --</p> <p>7 Q. I'm asking you for where in the report does</p> <p>8 Dr. Iakovlev say every brown spot is nerves?</p> <p>9 A. Nerves brown. What else?</p> <p>10 MR. SNELL: He just told you.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. Okay. Show me in the picture on page -- that</p> <p>13 you're on --</p> <p>14 A. Right.</p> <p>15 Q. -- the brown spots that are not nerves.</p> <p>16 A. Like here. In Figure 3a, page 18. Okay? We</p> <p>17 have --</p> <p>18 MR. FABRY: Just for the record, we're</p> <p>19 moving from page 12, Figure 1a, and now we're looking</p> <p>20 where?</p> <p>21 THE WITNESS: Page 18, 3a. Because it's</p> <p>22 continuous, right?</p> <p>23 A. Then after he explains Figure 1a, then sure in</p> <p>24 Figure 3a, he does not have to repeat what he wants to</p> <p>25 say. Then -- right?</p>

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<p>1 (By Ms. Thompson)</p> <p>2 Q. Do you think -- are you -- are you opining</p> <p>3 that Dr. Iakovlev is not competent to identify nerves</p> <p>4 with whatever stain?</p> <p>5 A. I think he used --</p> <p>6 Q. You can answer that yes or no and then</p> <p>7 explain.</p> <p>8 MR. SNELL: She asked the question. You</p> <p>9 can answer it however you want.</p> <p>10 MS. THOMPSON: You said he has to answer</p> <p>11 yes or no and then explain. Now you're saying --</p> <p>12 MR. SNELL: That's fine.</p> <p>13 She asked you a question.</p> <p>14 A. Yes. I think he somehow, you know, used S100</p> <p>15 staining just too much to -- he understands the</p> <p>16 limitation of S100 staining for the nerve staining.</p> <p>17 Meanwhile he still used that to make all the statements</p> <p>18 based on the staining results.</p> <p>19 (By Ms. Thompson)</p> <p>20 Q. And is there any portion of his report that he</p> <p>21 identifies nerves that you -- like any place where he</p> <p>22 points to nerves that you would say that is not a nerve?</p> <p>23 Is there any place in the report where</p> <p>24 Dr. Iakovlev points to a nerve that you are saying is not</p> <p>25 a nerve?</p>	<p>1 The record is getting jumbled with statements.</p> <p>2 (By Ms. Thompson)</p> <p>3 Q. Dr. Zheng, I actually don't think I ever got</p> <p>4 an answer to the question that was on the table, and that</p> <p>5 is, is there a place in this report where Dr. Iakovlev</p> <p>6 identifies a nerve that you disagree that that is, in</p> <p>7 fact, a nerve?</p> <p>8 And I'd really ask for a yes or no</p> <p>9 question, and then you can explain afterwards.</p> <p>10 A. First of all --</p> <p>11 MR. SNELL: If you need to take your time</p> <p>12 and go through every picture and every page, we'll do</p> <p>13 that. That's what she's asking you to do.</p> <p>14 A. I think whatever he point out, those brown</p> <p>15 stainings, I should say it's possibly nerve.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. It's possibly nerve?</p> <p>18 A. Right.</p> <p>19 Q. You can't say definitively that those are</p> <p>20 nerves?</p> <p>21 A. I cannot say definitively he's wrong or</p> <p>22 definitively he's right.</p> <p>23 Q. Okay. We'll move on.</p> <p>24 A. Okay?</p> <p>25 Q. Yup.</p>
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<p>1 A. But in many places I think some pictures are</p> <p>2 too low powered. It's difficult to say.</p> <p>3 But what I want to make the point is S100</p> <p>4 is not specific. I think he agreed on that. Right?</p> <p>5 Q. Oh, he will agree.</p> <p>6 A. He agreed.</p> <p>7 Q. I ask the questions. But I think he will</p> <p>8 agree that S100 is not specific.</p> <p>9 A. Right.</p> <p>10 Q. But he's not using it for specificity. He's</p> <p>11 using it for sensitivity so he can then go to a high</p> <p>12 power, find the nerves, identify the nerves</p> <p>13 morphologically, and count the nerves.</p> <p>14 A. So therefore --</p> <p>15 MR. SNELL: Is there a question, Counsel?</p> <p>16 MS. THOMPSON: He asked me a question. I</p> <p>17 was answering. But you're right, no, there was no</p> <p>18 question.</p> <p>19 MR. SNELL: Move to strike.</p> <p>20 MS. THOMPSON: Let's move on.</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. Okay. Let's move on to number --</p> <p>23 A. So I think my point basically is if --</p> <p>24 Q. There's no question on the table.</p> <p>25 MR. SNELL: She has to ask you a question.</p>	<p>1 In number two, your contention is that</p> <p>2 stress incontinence, dysuria, need to change position or</p> <p>3 initiate or complete emptying, nocturia are related to</p> <p>4 mesh migration and shrinkage has no scientific basis. Do</p> <p>5 you read that?</p> <p>6 A. Yes.</p> <p>7 Q. Such conclusions are subjective in nature.</p> <p>8 What's your basis for saying that those</p> <p>9 have no scientific basis?</p> <p>10 A. Because he did not provide scientific basis.</p> <p>11 He did not provide all these -- all the evidence saying</p> <p>12 this is scientific evidence.</p> <p>13 Q. Have you looked at Dr. Iakovlev's references</p> <p>14 on his reliance list attached to his report?</p> <p>15 A. I have looked some of them, yes, sure.</p> <p>16 Q. So how do you know that he does not have a</p> <p>17 basis for those opinions?</p> <p>18 And the question, what is your basis for</p> <p>19 saying that there is no basis for those -- for</p> <p>20 incontinence, dysuria --</p> <p>21 A. Because there is no evidence showing the mesh</p> <p>22 is migrating or migrating to certain positions from</p> <p>23 Edwards case, number one.</p> <p>24 Q. You're not aware of literature showing mesh</p> <p>25 migration?</p>

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<p>1 A. Mesh may be migrated, but what is evidence for</p> <p>2 Edwards case? He did not show.</p> <p>3 Q. Are you aware of literature with mesh erosion</p> <p>4 to the urethra?</p> <p>5 A. Mesh erosion, yes, has been reported.</p> <p>6 Q. Are you aware of literature with mesh movement</p> <p>7 from the mid urethra to the bladder neck?</p> <p>8 A. That has been reported but --</p> <p>9 Q. And could not -- could not that cause some of</p> <p>10 the symptoms that are described here by Dr. Iakovlev?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. But you cannot translate from --</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. Yes or no and then explain.</p> <p>15 A. Okay. Yes. From those particular situations,</p> <p>16 yes, you can explain those conditions. However, there is</p> <p>17 no evidence from Edwards case to support there is mesh</p> <p>18 migrating or mesh shrinking.</p> <p>19 Q. And you're aware of the literature describing</p> <p>20 mesh shrinkage, correct?</p> <p>21 A. I'm not sure I'm aware mesh will shrink.</p> <p>22 Q. You're not aware of mesh literature stating</p> <p>23 that mesh shrinks 20 to 50 percent?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. You mean the space or the material itself?</p>	<p>1 then without evidence of -- similar evidence to support</p> <p>2 for this particular patient, I don't know how can you</p> <p>3 conclude that. That's another thing.</p> <p>4 Q. So you're not aware of any articles that</p> <p>5 correlate the shrinkage and contraction of a</p> <p>6 transobturator tape with urinary symptoms?</p> <p>7 MR. SNELL: Form.</p> <p>8 Go ahead.</p> <p>9 A. I'm not aware of that.</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. But if that did exist, then your claim that</p> <p>12 Dr. Iakovlev's opinions has no scientific basis would be</p> <p>13 false, correct?</p> <p>14 A. No. Because, as I said, he said all these</p> <p>15 symptoms are related to the mesh migration and shrinking.</p> <p>16 That's the statement. Then he used this statement to</p> <p>17 refer to this particular patient. But meanwhile he did</p> <p>18 not provide evidence of shrinking as well as evidence of</p> <p>19 migration.</p> <p>20 Therefore, he used one concept from one</p> <p>21 place to apply to this particular patient. That's the</p> <p>22 reason I say there is no scientific basis.</p> <p>23 Q. So are you suggesting that if you have</p> <p>24 literature that says that a patient's symptom can be</p> <p>25 caused or is caused by a particular situation and you</p>
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<p>1 I'm not sure what you are referencing. Like mesh fiber</p> <p>2 filament from the certain thickness to --</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. Would you look at Exhibit -- the Cobb article.</p> <p>5 I don't recall what exhibit that is. The Argument for</p> <p>6 Lightweight Polypropylene Mesh in Hernia Repair.</p> <p>7 A. That's Exhibit 6.</p> <p>8 Q. And on page 67, degree of shrinkage, in that</p> <p>9 first paragraph, it states, All available meshes,</p> <p>10 regardless of their composition, experience a 20 to</p> <p>11 50 percent reduction in their initial size.</p> <p>12 Would you agree with that?</p> <p>13 A. Which sentence you are talking about?</p> <p>14 Q. Page 67, the paragraph head is Degree of</p> <p>15 Shrinkage. And it states, All available meshes,</p> <p>16 regardless of their composition, experience a 20 to</p> <p>17 50 percent reduction of their initial size.</p> <p>18 A. It's not clear whether it's the mesh fiber,</p> <p>19 like the diameter of the fiber, has been reduced to 20 to</p> <p>20 50 percent or the overall mesh fiber after implantation</p> <p>21 become reduced to size. I'm not sure.</p> <p>22 Q. Okay. I was just asking if the article stated</p> <p>23 that.</p> <p>24 A. Right. Then, again, for the articles like</p> <p>25 cited usually if you use the information from articles,</p>	<p>1 have a patient that has that same situation, that not --</p> <p>2 that you -- that if you make the opinion that in this</p> <p>3 patient that you're looking at her symptom is caused by</p> <p>4 the same situation, that that has no scientific basis?</p> <p>5 MR. SNELL: Form.</p> <p>6 Go ahead.</p> <p>7 (By Ms. Thompson)</p> <p>8 Q. Is that what you're saying?</p> <p>9 A. I think you can understand it that way. But I</p> <p>10 can give you another scenario. Many other patients,</p> <p>11 without any removal of those implants, they may have more</p> <p>12 or less same symptoms. Then can you say, okay, since you</p> <p>13 have these symptoms, you must have shrinking or migration</p> <p>14 of the mesh? Can you say that? No.</p> <p>15 Q. I believe you can have a different opinion,</p> <p>16 but can you say that it has no scientific basis when</p> <p>17 there are plenty of articles that address exactly this?</p> <p>18 That's my question.</p> <p>19 MR. SNELL: Form.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. Are you disagreeing with Dr. Iakovlev, or are</p> <p>22 you saying that he has no scientific basis?</p> <p>23 MR. SNELL: Form, foundation, asked and</p> <p>24 answered.</p> <p>25 A. Based on this particular patient, yes, he has</p>

<p style="text-align: right;">Page 194</p> <p>1 no scientific basis to say -- to make this statement. 2 (By Ms. Thompson) 3 Q. Okay. I'll leave it. 4 Number three, your opinion is that the -- 5 this pure scar thing, which I have not seen a definition 6 for in the literature, but you're saying that the 7 hardening and deformation does not occur until the scar 8 is mature? Am I interpreting that correctly? 9 MR. SNELL: No. Form. Move to strike 10 your earlier comment about your perusal of the 11 literature. And misstates his opinion. He says the 12 theory about mesh hardening and deformation. 13 (By Ms. Thompson) 14 Q. You can answer my question. 15 A. Can you repeat your question, please? 16 Q. You're saying that your findings do not 17 support Dr. Iakovlev's opinion that the hardening and 18 deformation of the mesh is induced by scar formation 19 within the mesh? 20 A. Correct. Basically we have -- I have found 21 good tissue integration within the mesh pores. Okay? 22 So, therefore, there is no pure scar formation. 23 Q. But there is fibrosis, correct? 24 A. As I said, we have fibrosis. We have a mild 25 degree of fibrosis.</p>	<p style="text-align: right;">Page 196</p> <p>1 (Marked for Identification: 2 Deposition Exhibit No. 16) 3 (By Ms. Thompson) 4 Q. So this is 21. It's not as good as the 5 picture electronically. 6 A. Right. 7 Q. But could you mark that with a Sharpie. And 8 if that's loose connective tissue, would you just write 9 LCT on that or whatever. 10 A. Then here is more dense, okay, DT. One is 11 LCT, one is -- 12 Q. Okay. And do you see what Dr. Iakovlev 13 identifies as congested vessels? 14 A. Yes. 15 Q. And would you agree that that is a congested 16 vessel -- 17 A. That's fine. 18 Q. -- vessels? 19 Okay. So go ahead and put on this one I 20 handed you the congested vessels. 21 A. He already point out. I agree that. 22 Q. Yeah. So just agree. You can still mark it 23 even if you agree on where you see congested vessels. 24 And would you agree with me that congested 25 vessels are often associated with edema?</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. And is there any areas that you can point me 2 to in either Dr. Iakovlev's or your slides that have 3 loose connective tissue? 4 And, if so, what percentage would you say 5 have loose connective tissue versus scar -- versus 6 fibrosis, which, at least by Robbins, is the same as 7 scar? 8 MR. SNELL: Form. 9 A. For instance, here, he interpret this area in 10 his Figure 5 on page 21, see on the top panel, we have 11 two mesh fibers. One is on the top, the other in the 12 bottom. Do you see that? 13 (By Ms. Thompson) 14 Q. 21, correct? 15 A. Yeah. Right? Okay. And then this area 16 basically showing here you can have loose connective 17 tissue. 18 Q. And so do you disagree with Dr. Iakovlev who 19 described that as edema? 20 A. I disagree because there's, you know, no 21 evidence saying this is edema. It's -- basically it's a 22 lucency of this area. Less fibro-connective tissue. 23 Q. And do you see the structures that -- 24 Actually, let me get that out. Page 21. 25</p>	<p style="text-align: right;">Page 197</p> <p>1 A. They can be associated. Can be also related 2 to the surgical procedure. 3 Q. Well, would it be related to the surgical 4 procedure a year or five years later? 5 A. Because -- yes, sure, sure. 6 Q. Unless there's mesh? 7 A. No. You have removed the specimen. Then 8 before specimen removed, then some area like vessels 9 being clamped to stop the bleeding, then those area may 10 represent congested vessels. Then as soon as congestion 11 is present, after fixation they are always present, so no 12 matter how many years later. 13 Q. Number four, Dr. Iakovlev performed a stretch 14 test. How can you tell from the pictures that the mesh 15 retained pores well over one thousand microns? Could you 16 please explain that to me? 17 A. Which one you are talking? Number four? 18 Q. Number four, your criticisms of Dr. Iakovlev's 19 report. 20 A. So he performed the test, the stretch test. 21 Basically I think he created by himself. I don't know. 22 I never see such a test being published in the 23 literature -- 24 Q. And I don't -- 25 A. -- as a valid kind of test for -- to test</p>

<p style="text-align: right;">Page 198</p> <p>1 whether this kind of material is stretchable or</p> <p>2 nonstretchable.</p> <p>3 Q. As a pathologist trying to determine the cause</p> <p>4 of a particular condition or situation, do you have to</p> <p>5 have a published protocol to do your experiment to help</p> <p>6 you understand what is going on with a patient's</p> <p>7 pathology?</p> <p>8 A. Oh, definitely. You need even IRB,</p> <p>9 Institutional Review Board, to approve for any test</p> <p>10 applied for the patient.</p> <p>11 Q. So if I gave you this and you were trying to</p> <p>12 understand how mesh works in the body, you would need IRB</p> <p>13 approval to stretch it and see what happened with the</p> <p>14 mesh?</p> <p>15 A. Nobody is doing that, because I -- based on my</p> <p>16 understanding these medical device, before release to the</p> <p>17 market, a proper test should have been done.</p> <p>18 Q. What tests?</p> <p>19 A. And, plus, as a pathologist, even single mesh</p> <p>20 you stretch them, then try to conclude something, these</p> <p>21 all nonsense, because you never can conclude something</p> <p>22 based on this kind of just pull and then say something,</p> <p>23 you know, this is the test. Say after stretching, then</p> <p>24 it will change the pore.</p> <p>25 Q. What tests were done on TVT-O before it came</p>	<p style="text-align: right;">Page 200</p> <p>1 MS. THOMPSON: We can break.</p> <p>2 THE VIDEOGRAPHER: Off the record 5:24.</p> <p>3 This concludes tape number four.</p> <p>4 (Recess taken.)</p> <p>5 THE VIDEOGRAPHER: On the record 5:36.</p> <p>6 This begins tape number five.</p> <p>7 THE WITNESS: Can I add something before</p> <p>8 you -- we proceed?</p> <p>9 MS. THOMPSON: Yes.</p> <p>10 THE WITNESS: Regarding S100 nerve-related</p> <p>11 issues, I think that Dr. Iakovlev's report, page 18,</p> <p>12 Figure 3a, and we discussed these brown spots present not</p> <p>13 only in the submucosal area, also I want to emphasize</p> <p>14 these brown spots also present in the squamous mucosa.</p> <p>15 Okay?</p> <p>16 And then this figure is relatively small,</p> <p>17 so within the similar field, I took the picture which</p> <p>18 presented in my report in Figure 6, and then this is</p> <p>19 blowup for that picture. See that? You can see these</p> <p>20 spots not only present in the sub -- this is squamous</p> <p>21 mucosa, these are submucosa area, which should have</p> <p>22 nerve. Then here in the mucosa should not have any</p> <p>23 nerve, but still has lots of brown spots. Okay? This is</p> <p>24 one point.</p> <p>25 And then to illustrate the point of S100</p>
<p style="text-align: right;">Page 199</p> <p>1 to market?</p> <p>2 A. These are very specific question. I don't</p> <p>3 know what kind of tests have been performed.</p> <p>4 Q. You don't know any tests that were done on</p> <p>5 TVT-O?</p> <p>6 A. That belongs to material. That's not in my</p> <p>7 specialty.</p> <p>8 Q. And you don't know any clinical testing done</p> <p>9 on TVT-O prior to being brought to market?</p> <p>10 A. I believe there have -- there have been like a</p> <p>11 safety test and then efficiency test and animal studies</p> <p>12 as well as some human population studies before that.</p> <p>13 Q. So what efficiency tests would have to be done</p> <p>14 prior to marketing?</p> <p>15 A. Again, I'm not in this field. You know,</p> <p>16 usually what specifically related to this question, I can</p> <p>17 tell you I don't know.</p> <p>18 Q. And what safety tests would need to be done</p> <p>19 before bringing it to market?</p> <p>20 A. Safety tests in general should have, first of</p> <p>21 all, it's safe. That means do not generate systemic or</p> <p>22 local toxicity for tissue, for human tissue. Okay?</p> <p>23 Q. And that would need to be human tissue,</p> <p>24 correct?</p> <p>25 A. Right. Correct.</p>	<p style="text-align: right;">Page 201</p> <p>1 is nonspecific, I used neurofilament staining, which</p> <p>2 shows in my report, I think Figure 7, page 16. This is</p> <p>3 relatively small one, so, therefore, this is a blowout</p> <p>4 picture.</p> <p>5 Here you can see the mucosa area and</p> <p>6 submucosa. Submucosa area it's a darker stain, it's</p> <p>7 relatively brown or black staining here. These identify</p> <p>8 very tiny nerve fibers. They're true nerve fibers, which</p> <p>9 is also based on morphology, not identifiable if I read</p> <p>10 H&E, because that's too small.</p> <p>11 However, they can be clearly identified by</p> <p>12 using neurofilament staining, which you can see within</p> <p>13 the mucosa, squamous mucosa, there is no any single black</p> <p>14 or neurofilament staining.</p> <p>15 (Marked for Identification:</p> <p>16 Deposition Exhibit No. 17)</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. We'll mark your neurofilament as 17.</p> <p>19 But you will agree with me that the only</p> <p>20 nerves that Dr. Iakovlev comments on as nerves are those</p> <p>21 here in the submucosa? He doesn't say anything about</p> <p>22 anything in the mucosa, correct? Is that correct?</p> <p>23 A. It's partially correct. Mainly because he</p> <p>24 also said all these brown stainings are -- nerve stains</p> <p>25 brown.</p>

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<p>1 Q. Okay. I'm just going to read the caption on</p> <p>2 that figure that you have shown us, and it says,</p> <p>3 Ms. Edwards' specimen. The nerves are running between</p> <p>4 the hard mesh and the mucosa. At this location an</p> <p>5 external pressure intercourse can compress the nerves</p> <p>6 against the hardened mesh.</p> <p>7 And, Dr. Zheng, at the break I promised --</p> <p>8 A. I --</p> <p>9 Q. There's no question on the table.</p> <p>10 A. I understand. But I did not finish my</p> <p>11 statement yet.</p> <p>12 Q. I just have a certain amount of time, so I'm</p> <p>13 going to ask that we move on.</p> <p>14 A. Okay.</p> <p>15 Q. And I also promised the court reporter at the</p> <p>16 break that we would try to do better about not</p> <p>17 interrupting each other and talking over each other, so</p> <p>18 let's try to do that.</p> <p>19 A. Okay. So which page?</p> <p>20 Q. Does pressure on a nerve cause pain?</p> <p>21 A. Which page we at?</p> <p>22 Q. I'm not on a page. I'm just asking a</p> <p>23 question.</p> <p>24 A. Okay.</p> <p>25 Q. Does pressure on a nerve cause pain?</p>	<p>1 polypropylene is nondegradable in a human body?</p> <p>2 A. Because what I have seen from my practice, I</p> <p>3 did not see any evidence of these degradation.</p> <p>4 Q. Have you looked for degradation in your</p> <p>5 practice?</p> <p>6 A. I looked from under microscope.</p> <p>7 Q. And what would you -- what were you looking</p> <p>8 for?</p> <p>9 A. For instance, degradation is typically like</p> <p>10 missing a piece, right? Number one.</p> <p>11 Number two is irregular in certain area or</p> <p>12 surface area become irregularity. All right? Then some</p> <p>13 maintains like -- or partially at least maintain the mesh</p> <p>14 property.</p> <p>15 Q. Have you looked for surface area</p> <p>16 irregularities in your practice?</p> <p>17 A. Yes.</p> <p>18 Q. How?</p> <p>19 A. Under microscope, turn on a higher power.</p> <p>20 Q. Have you looked at surface irregularities</p> <p>21 under electron microscope?</p> <p>22 A. No.</p> <p>23 Q. And what is your -- what is the basis for your</p> <p>24 opinion that -- so the basis for your opinion that it's</p> <p>25 nondegradable is your personal experience of looking for</p>
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<p>1 A. Pressure on nerve, in general, can cause pain.</p> <p>2 Q. And how many nerves does it take to cause</p> <p>3 pain?</p> <p>4 A. How many nerves? I can't quantify how many</p> <p>5 nerves can cause pain. I'm not in the field to tell you</p> <p>6 or to answer this question.</p> <p>7 Q. So you can't say one way or the other how many</p> <p>8 nerves you have to have to cause pain?</p> <p>9 A. I can't say that.</p> <p>10 Q. Can one nerve cause pain?</p> <p>11 A. If you want to say like, in general, can nerve</p> <p>12 cause pain, then yes. Then meanwhile, without nerve, can</p> <p>13 the patient feel pain? Also yes.</p> <p>14 Q. Are you a pain expert?</p> <p>15 A. No.</p> <p>16 Q. Does polypropylene degrade in the human body?</p> <p>17 A. Based on my understanding, polypropylene mesh</p> <p>18 is considered as a nondegradable biomaterial, number one.</p> <p>19 Number two, even they have sort of -- I'm</p> <p>20 aware the literature, some literature saying possible</p> <p>21 degradations. Then this amount of degradation, based on</p> <p>22 my understanding, is not going to cause overall property</p> <p>23 of the mesh. Therefore, it's not going to cause</p> <p>24 functional change.</p> <p>25 Q. And what is your basis for saying that</p>	<p>1 degradation under the microscope, correct?</p> <p>2 A. Correct.</p> <p>3 Q. What was the methodology that you used for</p> <p>4 that?</p> <p>5 A. I just used my eye, observe.</p> <p>6 Q. So you eyeballed it to see?</p> <p>7 A. Eyeballed it, right.</p> <p>8 Q. And the opinion that if it were to occur, that</p> <p>9 you say that there's some literature that it might -- did</p> <p>10 I represent that correctly? That it would not cause any</p> <p>11 functional change; is that correct?</p> <p>12 A. Correct.</p> <p>13 Q. And what's your basis for that opinion?</p> <p>14 A. Because, for instance, if you -- if somebody</p> <p>15 magnify into electron microscopic level, that means maybe</p> <p>16 several thousand magnifications, then that means you are</p> <p>17 looking for very tiny, tiny areas. These tiny areas is</p> <p>18 not going to change the overall situation.</p> <p>19 Q. Are you aware that polymers, plastics,</p> <p>20 including polypropylene, harden when there's surface</p> <p>21 degradation?</p> <p>22 MR. SNELL: Foundation.</p> <p>23 A. I believe, in general, all these plastic</p> <p>24 material, you know, exposed to environment to certain</p> <p>25 time period, yes, they may change and become hardened or</p>

<p style="text-align: right;">Page 206</p> <p>1 change their physical property. That's in general, yes. 2 (By Ms. Thompson) 3 Q. As a pathologist, would you agree that if 4 there's degradation, it would perpetuate an inflammatory 5 response or exaggerate an inflammatory response? 6 MR. SNELL: Form. 7 A. I have no evidence to say yes or no. 8 (By Ms. Thompson) 9 Q. So you don't know one way or the other? 10 A. Correct. 11 Q. Do you feel like surface degradation and 12 cracking would -- could harbor bacteria in the surface of 13 the mesh? 14 A. I have no evidence to say. 15 Q. You have no opinion one way or the other? 16 A. Correct. 17 MS. THOMPSON: I'm going to show you 18 representative articles of degradation, and I want your 19 opinion on whether these articles say that degradation 20 may be possible or whether they say degradation occurs. 21 I'm going to mark this as Exhibit 18. 22 It's Costello's article, Materials Characterization of 23 Explanted Polypropylene Hernia Meshes. 24 (Marked for Identification: 25 Deposition Exhibit No. 18)</p>	<p style="text-align: right;">Page 208</p> <p>1 A. It says in that way, that's true. 2 Q. In the introduction, second paragraph, it 3 says, There are many potential sources of chronic pain, 4 including stiffening of the abdominal wall due to an 5 intense inflammatory reaction to the mesh material. In 6 addition, nerve damage may result in entrapment into the 7 scar tissue or from the mesh fixation method utilized in 8 the surgical procedure. It is possible that an ongoing 9 inflammatory response to the permanent implant is 10 responsible for these complications. 11 Is that what it says? 12 A. This paper says in that way. 13 Q. And when was this published? 14 A. I believe that's 2007. 15 Q. And there are pictures contained in this 16 article, scanning electron micrographs, of polypropylene 17 mesh with transverse cracks, blisters and peeling fibers. 18 Would you agree? 19 MR. SNELL: Foundation. 20 A. I'm not expert to evaluate these photographs 21 whether, you know, these are truly cracks or not cracks. 22 MS. THOMPSON: I'm going to give you 23 another article. This is one by Clave that specifically 24 looks at mesh explants from transvaginal surgery. 25</p>
<p style="text-align: right;">Page 207</p> <p>1 (By Ms. Thompson) 2 Q. And without going through the entire article, 3 could you just read the last sentence of the abstract. 4 A. Yes, I did. 5 Q. And what does it say? 6 A. It says the results overall supported the 7 hypothesis that oxidation is involved with the 8 degradation of polypropylene hernia mesh materials. 9 Here several things are different. One is 10 this is hernia mesh. The other is I don't know what kind 11 of study method they are using. And then what is the 12 results they are getting. Okay? Then also whether these 13 findings correlate to the overall function of the mesh. 14 So all these questions are unanswered. 15 Therefore, I'm not able to provide my opinion regarding 16 this article. 17 Q. In the abstract it also says there are several 18 complications associated with the use of mesh that may be 19 due to the chronic inflammatory reaction to the mesh or a 20 loss of compliance after degradation of the material. 21 Is that what the abstract says? 22 A. Abstract says in that way. 23 Q. And mesh contraction and migration can also 24 occur, sometimes resulting in recurrence, at least for 25 hernia. Is that what it says?</p>	<p style="text-align: right;">Page 209</p> <p>1 (Marked for Identification: 2 Deposition Exhibit No. 19) 3 (By Ms. Thompson) 4 Q. And what is the title of this article? 5 A. The title says, Polypropylene mesh as a 6 reinforcement in pelvic surgery is not inert: 7 Comparative study of 100 explants. 8 Q. And this article also includes pictures 9 demonstrating degradation on the surface of various 10 different kinds of mesh, correct? 11 MR. SNELL: Foundation. 12 (By Ms. Thompson) 13 Q. On page 263, there are several different kinds 14 of mesh listed, and then there are pictures, the intact 15 column and a degraded column, correct? 16 A. Based on that article, they list it in that 17 way. 18 Q. And in the last -- in the conclusion, the 19 second paragraph, it says, The polypropylene implants 20 degraded more in the presence of an acute infection or 21 chronic inflammation. Is that what that says? 22 A. It say so. 23 (Marked for Identification: 24 Deposition Exhibit No. 20) 25</p>

<p style="text-align: right;">Page 210</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Another article is Exhibit 20. Could you read</p> <p>3 me the title of that article?</p> <p>4 A. Comparison of the In Vivo Behavior of</p> <p>5 Polyvinylidene Fluoride and Polypropylene Suture Used in</p> <p>6 Vascular Surgery.</p> <p>7 Q. You did better than I would have done.</p> <p>8 And at the bottom of that page, you'll see</p> <p>9 a number that says ETH.MESH with a number. Would you</p> <p>10 just read that, also?</p> <p>11 A. In abstract?</p> <p>12 Q. On the front page at the bottom left-hand</p> <p>13 corner.</p> <p>14 MR. SNELL: There is no F mesh. What are</p> <p>15 you talking about?</p> <p>16 MS. THOMPSON: I believe the one marked as</p> <p>17 an exhibit does. That one must have been cut off in the</p> <p>18 printer.</p> <p>19 THE WITNESS: I don't know if you --</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. Let me see the front of your...</p> <p>22 Yeah. Would you just read this right</p> <p>23 here?</p> <p>24 A. Oh. Yeah. ETH dot MESH dot these numbers.</p> <p>25 Q. Could you read the numbers?</p>	<p style="text-align: right;">Page 212</p> <p>1 that way, because it say so.</p> <p>2 (By Ms. Thompson)</p> <p>3 Q. And then on the very last page, the first</p> <p>4 paragraph, it says, The phenomenon of surface oxidation</p> <p>5 is one -- only one of a series of steps in the</p> <p>6 degradation process.</p> <p>7 It goes on to say that the degradation of</p> <p>8 polypropylene monofilaments involves surface</p> <p>9 embrittlement and crack formation and the loss of</p> <p>10 mechanical properties.</p> <p>11 What does surface embrittlement mean?</p> <p>12 MR. SNELL: Form.</p> <p>13 Go ahead.</p> <p>14 (By Ms. Thompson)</p> <p>15 Q. To you?</p> <p>16 A. To me, that means maybe make it very easy to</p> <p>17 get cracked. Is that right?</p> <p>18 Q. So as it cracks, it becomes easier to crack?</p> <p>19 Is that what you're saying?</p> <p>20 A. I think so. That's what that means.</p> <p>21 Q. And what does it mean by the loss of</p> <p>22 mechanical properties?</p> <p>23 A. So from these wordings or phrases, basically</p> <p>24 the original physical property has been changed. That</p> <p>25 means loss of these physical properties.</p>
<p style="text-align: right;">Page 211</p> <p>1 A. 0584559.</p> <p>2 Q. And did you already say when the article was</p> <p>3 published? I can't remember.</p> <p>4 A. That's in 1997.</p> <p>5 Q. And would you agree that polypropylene mesh is</p> <p>6 the same material as Prolene suture? Prolene mesh is</p> <p>7 polypropylene or Prolene suture?</p> <p>8 MR. SNELL: Form.</p> <p>9 Go ahead.</p> <p>10 A. I think I have that impression. They're the</p> <p>11 same material.</p> <p>12 (By Ms. Thompson)</p> <p>13 Q. And could you read just the last couple of</p> <p>14 sentences of the abstract, starting with, After one and</p> <p>15 two years in vivo?</p> <p>16 A. After one and two years in vivo, the explanted</p> <p>17 polypropylene sutures showed visual evidence of surface</p> <p>18 stress cracking. This was not found within the explanted</p> <p>19 polyvinylidene fluoride sutures.</p> <p>20 Q. And this article also provides pictures that</p> <p>21 didn't reproduce very well but that also show surface</p> <p>22 changes in Prolene suture, correct, explanted Prolene</p> <p>23 suture?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. I think, based on this article, you can say</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. And that would occur with a material that</p> <p>2 degrades, that the physical properties change, correct?</p> <p>3 A. Based on that article.</p> <p>4 MR. SNELL: Form.</p> <p>5 MS. THOMPSON: I'm going to hand you a</p> <p>6 stack of articles -- a stack of documents that I don't</p> <p>7 have stapled together, and I should.</p> <p>8 Does anybody have a paper clip?</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. And what is the letterhead on these documents</p> <p>11 that I just handed to you, Dr. Zheng?</p> <p>12 A. It says, Crack depth in explanted Prolene</p> <p>13 polypropylene sutures.</p> <p>14 Q. And what is at the very top of the document as</p> <p>15 far as the letterhead of the company?</p> <p>16 A. That's Ethicon.</p> <p>17 Q. Okay. And the date of the document that</p> <p>18 you're looking at?</p> <p>19 A. That's June 15, 1982.</p> <p>20 THE COURT REPORTER: Are you marking this</p> <p>21 one?</p> <p>22 MS. THOMPSON: Yes. I'm going to mark</p> <p>23 that whole stack. I was kind of waiting until I got a</p> <p>24 paper clip.</p> <p>25 Sorry, Dr. Zheng. Would you mind handing</p>

<p style="text-align: right;">Page 214</p> <p>1 me yours back. Thank you.</p> <p>2 (Marked for Identification:</p> <p>3 Deposition Exhibit No. 21)</p> <p>4 MR. SNELL: What number?</p> <p>5 Twenty-one, you said?</p> <p>6 MS. THOMPSON: I think Dr. Zheng's were in</p> <p>7 a little different order from mine and maybe even from</p> <p>8 yours, too. We'll go ahead and find it as he does it.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. So the title of this document from Ethicon in</p> <p>11 1982 was Crack Depth in Explanted Prolene Polypropylene</p> <p>12 Sutures, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And the purpose of the study was, just reading</p> <p>15 from the first line, to determine the best estimates for</p> <p>16 the penetration depth of surface cracks, correct?</p> <p>17 A. I believe so, yes.</p> <p>18 Q. And would you just read to me the beginning of</p> <p>19 the paragraph, next paragraph that starts with the 10-0</p> <p>20 sutures?</p> <p>21 A. 10-0 sutures showed surface cracks after one</p> <p>22 to two years implantation; in the larger sutures after</p> <p>23 seven and a half years but not at a five, although -- in</p> <p>24 parentheses, although cracks could be induced by abrasion</p> <p>25 on the five-year explant, as previously reported by</p>	<p style="text-align: right;">Page 216</p> <p>1 A. No. I don't want to go too far, because I</p> <p>2 already stated I'm not expert -- material expert, so this</p> <p>3 is beyond my expertise. I'm a pathologist. Right? You</p> <p>4 are asking bunch of questions regarding whether these</p> <p>5 tests or related things can prove whether there is --</p> <p>6 this material is degradable or not. I'm not able to</p> <p>7 answer that, because I don't have expertise for this.</p> <p>8 (By Ms. Thompson)</p> <p>9 Q. So degradation -- you would consider</p> <p>10 degradation to be beyond your expertise?</p> <p>11 A. Overall, for this situation, yes, for this</p> <p>12 particular situation. I don't mean for everything.</p> <p>13 Q. So you don't intend to give any opinions about</p> <p>14 degradation in the Edwards and Huskey trials?</p> <p>15 A. That's not true, because Dr. Iakovlev already</p> <p>16 mentioned bark-like issues. He provide the pictures</p> <p>17 demonstrate the bark. And then based on my experience, I</p> <p>18 examined those. Then also I showed -- used his same</p> <p>19 methods, like polarization versus nonpolarization</p> <p>20 conditions. Then I can't, you know, repeat his</p> <p>21 observation, then meanwhile provide my observation to</p> <p>22 that.</p> <p>23 If he is thinking that kind of bark-like</p> <p>24 material represents degradation, then basically I can say</p> <p>25 there is no convincing evidence at all, because I can</p>
<p style="text-align: right;">Page 215</p> <p>1 Dr. Borysko.</p> <p>2 Q. What does that mean to you?</p> <p>3 A. I think basically these sentence means the</p> <p>4 sutures may have showed evidence of surface cracks,</p> <p>5 basically.</p> <p>6 Q. And are surface cracks an indication of</p> <p>7 degradation?</p> <p>8 MR. SNELL: Form.</p> <p>9 A. I can't look at this equal, because I don't</p> <p>10 know, number one.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. So you don't know if degradation causes</p> <p>13 surface cracks?</p> <p>14 A. I don't know that. All right? Then, also, I</p> <p>15 think all these synthetic material, if I use a scenario</p> <p>16 like tires in a car, these tires, after running for a</p> <p>17 while, then you have -- you have to replace. They get</p> <p>18 wear and tear. That's the situation. I understand</p> <p>19 everything getting old have to be replaced. It's not</p> <p>20 like, you know, if you are putting outside and even you</p> <p>21 are exposing to sunshine, then everything get oxidized or</p> <p>22 degraded.</p> <p>23 Q. So you're comparing this to wear and tear of</p> <p>24 the polypropylene suture over time, correct?</p> <p>25 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 217</p> <p>1 simply explain those bark-like area actually is better</p> <p>2 interpreted as degenerated collagen bundles.</p> <p>3 Q. Okay. Well, let's -- that's the next thing I</p> <p>4 was going to do anyway.</p> <p>5 A. It's better that way.</p> <p>6 Q. Okay. So we'll go to that. But anything</p> <p>7 related to materials and polypropylene degradation, you</p> <p>8 don't feel like you're qualified to testify about that?</p> <p>9 A. Correct.</p> <p>10 Q. All right. Let's go to page 58, if you want</p> <p>11 to have the -- of Dr. Iakovlev's report, if you want to</p> <p>12 have clearer pictures, but I'm also going to be handing</p> <p>13 you --</p> <p>14 A. 58?</p> <p>15 Q. 58. If you would look at this picture.</p> <p>16 MR. SNELL: Does it have a legend in the</p> <p>17 report?</p> <p>18 MS. THOMPSON: No. I'm showing the</p> <p>19 photograph.</p> <p>20 MR. FABRY: TE1 is the figure.</p> <p>21 MS. THOMPSON: And this is TE1. This is</p> <p>22 from Tonya Edwards' case.</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. What do you see in this picture?</p> <p>25 A. This picture basically shows -- it's a lower</p>

<p style="text-align: right;">Page 218</p> <p>1 power, first of all, showing mesh fiber and mesh fiber</p> <p>2 with spaces as well as fibro-connective tissue.</p> <p>3 Q. And do you -- okay. Let's look at the</p> <p>4 fibro-connective tissue.</p> <p>5 A. Yes.</p> <p>6 Q. And use your marker, and I assume you are</p> <p>7 calling that fibrosis, correct?</p> <p>8 A. This is very lower power. Okay?</p> <p>9 Q. So from that power you can't determine what --</p> <p>10 A. Basically I say it's a soft tissue or</p> <p>11 fibro-connective tissue in the lower power. Then if you</p> <p>12 want to estimate or give the evaluation of the degree of</p> <p>13 fibrosis, then you need to turn on higher power then to</p> <p>14 identify those cellular components.</p> <p>15 Q. Okay. So do you agree with Dr. Iakovlev that</p> <p>16 this represents deformed curled mesh?</p> <p>17 A. No, I do not agree. I disagree.</p> <p>18 Q. And explain to me what you think it</p> <p>19 represents.</p> <p>20 A. This can simply represent the tangential cut</p> <p>21 of the mesh fiber.</p> <p>22 Q. Explain to me how you get a tangential cut of</p> <p>23 the mesh fiber that has some of the areas where the fiber</p> <p>24 were circular and some areas of the fiber length-wise?</p> <p>25 A. Because --</p>	<p style="text-align: right;">Page 220</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. So the fibers of the mesh are encased in scar,</p> <p>3 but when you put it in formalin, it can cause it to curl</p> <p>4 and deform as a result of the formalin. Is that what</p> <p>5 you're saying?</p> <p>6 A. Right.</p> <p>7 MR. SNELL: Form.</p> <p>8 A. Let's put things in a simple way. You</p> <p>9 have fresh tissue. Okay. Is one shape, like a string.</p> <p>10 You remove the tape from that particular patient, it's</p> <p>11 one piece of tissue. Then after fixation, then one piece</p> <p>12 of tissue will change shape for sure.</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. How do you get mesh fibers running</p> <p>15 perpendicular to the vaginal surface, the vaginal mucosa,</p> <p>16 if there's no deformation?</p> <p>17 MR. SNELL: Foundation on that.</p> <p>18 A. Because I think if you -- you have to</p> <p>19 understand those so-called...</p> <p>20 All right. In my report, Figure 1, TVT</p> <p>21 mesh. All right? This is a perfect condition. It's</p> <p>22 before implant. Yeah, just like that. Okay?</p> <p>23 And then you can imagine after the tape</p> <p>24 implanted into human tissues, they already change some</p> <p>25 shape in certain degree. Do you understand that?</p>
<p style="text-align: right;">Page 219</p> <p>1 MR. SNELL: Form.</p> <p>2 Go ahead.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. If the mesh is not curled?</p> <p>5 A. Okay. First of all, curled or not curled</p> <p>6 is -- should be estimate or evaluated with an in vivo</p> <p>7 condition. This is already explanted material. As you</p> <p>8 can see from one of these gross pictures, that picture,</p> <p>9 that picture is after explant from the patient body. The</p> <p>10 tissue already being fixed into the formalin for a long</p> <p>11 time.</p> <p>12 Then this fixation will create lots of</p> <p>13 artifact, because the fixation process will get rid of</p> <p>14 the water, number one; number two, will make the protein</p> <p>15 cross linking to each other, therefore will change the</p> <p>16 original position of the mesh. Therefore, you see</p> <p>17 these -- some of these tissues is not straight. They</p> <p>18 curve.</p> <p>19 Q. So you're saying that formalin can actually</p> <p>20 cause mesh that's encased in scar to curl after it's</p> <p>21 removed from the body? Is that what you're saying?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. Yes. The fixation process will change, that's</p> <p>24 number one, yes, for sure.</p> <p>25</p>	<p style="text-align: right;">Page 221</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. I'm going to hand you this piece of TVT mesh.</p> <p>3 MR. SNELL: I'm going to object to this</p> <p>4 demonstrative, which is totally unscientific and</p> <p>5 certainly it hasn't been implanted.</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. I want you to take --</p> <p>8 MR. SNELL: Hold on. It hasn't been</p> <p>9 implanted. And it certainly has no relevance or bearing</p> <p>10 to Mrs. Edwards or Mrs. Huskey, for that matter. There</p> <p>11 is no reliable scientific indicia that this is</p> <p>12 representative of these particular cases for whatever</p> <p>13 this demonstrative is, and I'm actually going to object.</p> <p>14 (By Ms. Thompson)</p> <p>15 Q. Take the scissors, Dr. Zheng, and cut a</p> <p>16 portion of the mesh. And let's not use this part. Let's</p> <p>17 use this fresh part that still has the sheath on it. Cut</p> <p>18 a piece --</p> <p>19 MR. SNELL: Hold on. No, he's not cutting</p> <p>20 mesh. He's not here to perform science experiments for</p> <p>21 you. He's here to answer your questions. So you can</p> <p>22 take that back. That's not going to happen in my</p> <p>23 deposition.</p> <p>24 (By Ms. Thompson)</p> <p>25 Q. All right. I'm going to cut the mesh and hand</p>

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<p>1 you a piece of mesh. It's covered with a plastic sheath</p> <p>2 that I'm going to remove.</p> <p>3 And as a pathologist, I want you just to</p> <p>4 hold that piece of mesh and tell me what the edges feel</p> <p>5 like.</p> <p>6 A. The edge is not smooth.</p> <p>7 Q. Is it sharp?</p> <p>8 MR. SNELL: Form.</p> <p>9 A. I don't think it can be considered as sharp.</p> <p>10 (By Ms. Thompson)</p> <p>11 Q. Is it soft?</p> <p>12 A. Overall the mesh is soft.</p> <p>13 Q. The edges, are the edges soft?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. You have some kind of pointings.</p> <p>16 But I think your original question was</p> <p>17 asking what's my interpretation why some of these mesh</p> <p>18 perpendicular to the others, right?</p> <p>19 (By Ms. Thompson)</p> <p>20 Q. Okay. That's not a question on the table.</p> <p>21 Go ahead and pull that mesh just a little</p> <p>22 bit yourself.</p> <p>23 MR. SNELL: No, no, no. You're not doing</p> <p>24 that.</p> <p>25 This is not an experiment. It's a</p>	<p>1 feel the mesh that you're testifying about today?</p> <p>2 A. Before surgery, I don't do that, because when</p> <p>3 I examine the specimen, that's explanted material.</p> <p>4 Q. Okay. Let's move to --</p> <p>5 A. But I did not answer your question regarding</p> <p>6 the perpendicular situation, because we were interrupted</p> <p>7 by other questions.</p> <p>8 Q. Okay. How do you explain the perpendicular</p> <p>9 orientation of mesh?</p> <p>10 A. So perpendicular interpretation is you can see</p> <p>11 this picture, see these knitted area, original, just like</p> <p>12 you have. This is a blowup so you can see better. Then</p> <p>13 you have these knots area. These knotted area, if you</p> <p>14 cut in the tangential or perpendicular way, then you see</p> <p>15 these different shape of the mesh fibers, and they cross</p> <p>16 link to each other.</p> <p>17 Q. And my question is, how can you cut a mesh</p> <p>18 that's embedded in formalin, encased in fibrosis, in a</p> <p>19 way to get some of the fibers cross sectioned and some of</p> <p>20 the fibers length-wise and some of the fibers in every</p> <p>21 other which way?</p> <p>22 MR. SNELL: Hold on. Form. I'm going to</p> <p>23 object on foundation, too, because we don't know what</p> <p>24 your person did with it.</p> <p>25</p>
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<p>1 deposition. You can ask him questions.</p> <p>2 MS. THOMPSON: I can hand him a piece of</p> <p>3 TVT mesh and --</p> <p>4 MR. SNELL: No. He is not going to be</p> <p>5 stretching the mesh.</p> <p>6 Dr. Zheng, you can give it back to her.</p> <p>7 MS. THOMPSON: Okay. Well, let the record</p> <p>8 reflect --</p> <p>9 MR. SNELL: That's fine.</p> <p>10 MS. THOMPSON: -- that I --</p> <p>11 MR. SNELL: I will put on the record --</p> <p>12 MS. THOMPSON: I'm talking.</p> <p>13 MR. SNELL: -- I gave it back to you. I</p> <p>14 gave it back to you. We're not here to do experiments</p> <p>15 for you. We're here to answer questions. This is a</p> <p>16 legal proceeding, a deposition; it's questions asked, he</p> <p>17 answers them.</p> <p>18 MS. THOMPSON: And the legal proceeding is</p> <p>19 about the piece of mesh that I just handed to Dr. Zheng.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. Dr. Zheng, have you ever felt a TVT mesh</p> <p>22 before, before today when I just handed you this one?</p> <p>23 A. No, because there is no reason for me to do</p> <p>24 this.</p> <p>25 Q. Okay. So there's no reason for you to see or</p>	<p>1 (By Ms. Thompson)</p> <p>2 Q. Is it possible to deform a mesh when you put</p> <p>3 it into the paraffin processor?</p> <p>4 A. After fixation process --</p> <p>5 Q. That's not my question. Is it possible to</p> <p>6 deform the mesh when you put it in the tissue processor?</p> <p>7 MR. SNELL: You mean in the machine?</p> <p>8 MS. THOMPSON: Yes.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. For the person that's putting the mesh in the</p> <p>11 tissue processor to actually deform the mesh as it's put</p> <p>12 in, before it's put in?</p> <p>13 A. No. I don't think that the machine will cause</p> <p>14 this problem. However --</p> <p>15 Q. Let's move on to the next question. Let's</p> <p>16 look at Figure, on page 59, TE2.</p> <p>17 THE COURT REPORTER: Are you marking</p> <p>18 these? You didn't mark the last one.</p> <p>19 MS. THOMPSON: Oh, I need a new batch.</p> <p>20 Thank you.</p> <p>21 (Marked for Identification:</p> <p>22 Deposition Exhibit No. 22)</p> <p>23 MR. SNELL: Is that 22?</p> <p>24 MS. THOMPSON: Yes.</p> <p>25</p>

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<p>1 (Marked for Identification: 2 Deposition Exhibit No. 23) 3 (By Ms. Thompson) 4 Q. And this is also a slide from Tonya Edwards' 5 case, correct? 6 A. Correct. 7 Q. And this is actually what we were discussing 8 about the mesh being perpendicular to the surface, 9 correct? 10 A. But based on what he says, correct. 11 Q. And is it your opinion that this orientation 12 of the mesh to the vaginal mucosa, in other words, 13 perpendicular to the vaginal mucosa, is caused by the 14 fixation process? 15 A. I think he presented this picture in a totally 16 wrong concept, okay, because the surgeon removed the 17 mesh. First of all, in vivo condition the surgeon 18 removed the mesh. He never describe any like migration 19 or become -- mesh become perpendicular. 20 The mesh, this gross picture, this mesh is 21 like five to six centimeter in size. If it's 22 perpendicular, that means the mesh is going to penetrate 23 from anterior vaginal wall to the posterior wall or to 24 the skin. That's six centimeter size perpendicular. 25 How that can happen? Right? Do you</p>	<p>1 example of the mesh associated with the mucosa. Because 2 when the surgeon cut the mesh, then one end or one part 3 was part of the mucosa is very normal procedure. Okay? 4 You have to cut it open, then remove, then some of the 5 end will attach to the -- one end will attach to the 6 mucosa. That's very reasonable. 7 (By Ms. Thompson) 8 Q. Isn't this mesh encased in fibrosis? 9 A. As I said, the degree of fibrosis is mild. 10 Q. But this isn't free-floating mesh. You would 11 agree with that, wouldn't you? 12 A. It's not free floating. It's -- this mesh 13 perfectly has very good tissue integration. 14 Q. So you're saying that this orientation to the 15 mucosa occurred after explant? 16 A. No. That's in vivo condition. That's fine. 17 But just because of particular cut, then he said, oh, 18 because the location is perpendicular to the mucosa, then 19 the mesh is perpendicular. This is very ridiculous. 20 Q. This portion of the mesh -- 21 MR. SNELL: Don't interrupt him. He was 22 about to tell you why it's ridiculous. 23 A. You can ask other pathologists. People will 24 laugh. What are you talking about this is perpendicular? 25 So that's very simple.</p>
Page 227	Page 229
<p>1 understand what I'm talking? 2 Q. I'm -- can you look at that mesh and see how 3 it's curled? And if you have a mesh that's curled under 4 a mucosa, that's going to be perpendicular, correct? 5 MR. SNELL: Foundation, form. 6 A. No. He said -- what he said perpendicular is 7 this like mucosa, then this mesh. 8 (By Ms. Thompson) 9 Q. No. What he's saying is this is the mucosa. 10 The mesh is curled. So if you section it in this area, 11 you're having curled mesh perpendicular to the mucosa. 12 I don't think anybody says the mesh is 13 coming in perpendicular. 14 MR. SNELL: Hold on. Form and foundation 15 on your interpretation of what Dr. Iakovlev said and what 16 he's done with this mesh. 17 (By Ms. Thompson) 18 Q. Okay. What is your explanation for the 19 appearance of perpendicular mesh in this? I don't want 20 what Dr. Iakovlev says. I want your interpretation of 21 why the mesh is perpendicular in this photo. 22 MR. SNELL: Foundation. 23 Go ahead. 24 A. First of all, I never understand this is 25 perpendicular, because there is no -- this is perfect</p>	<p>1 MS. THOMPSON: All right. We'll see on 2 that. 3 I can skip the one on striated muscle. 4 Turn to page 63, and I'll mark that. 5 (Marked for Identification: 6 Deposition Exhibit No. 24) 7 (By Ms. Thompson) 8 Q. Do you agree with Dr. Iakovlev -- this is TE5, 9 Tonya Edwards' case -- that these are examples of 10 thrombosed capillaries? 11 A. I think -- 12 MR. SNELL: Hold on before you answer 13 that. 14 Foundation. 15 Go ahead. 16 A. Okay. From TE5, Figure TE5, in the right 17 panel, that vessel from this picture can be considered as 18 thrombosed. But the other one in the left panel also can 19 be interpreted as congested, because as we discussed in 20 other picture, they look very much similar. Okay? So 21 from those pictures I can say. 22 (By Ms. Thompson) 23 Q. So the right-hand side is thrombosed. The 24 left-hand side could be either thrombosed or congested. 25 Is that what you're saying?</p>

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<p>1 A. Correct. Based on these pictures.</p> <p>2 Q. And is that edematous tissue surrounding those</p> <p>3 thrombosed capillaries?</p> <p>4 A. Can be either edema or loose connective</p> <p>5 tissue, as I told you. For instance, in the left -- in</p> <p>6 the right upper corner of the right panel, okay, shows</p> <p>7 these lucency of the collagen bundles there and some</p> <p>8 cells. Therefore, this can be either loose connective</p> <p>9 tissue or you can say edema. But it's very blowup</p> <p>10 picture. You don't know overall situation.</p> <p>11 (Marked for Identification:</p> <p>12 Deposition Exhibit No. 25)</p> <p>13 (By Ms. Thompson)</p> <p>14 Q. Let's go to page 65. And I'm handing you</p> <p>15 Exhibit 25, which is the left-hand side of this.</p> <p>16 First of all, would you identify the S100</p> <p>17 stained structures as nerves in this picture?</p> <p>18 A. I see some brown stainings based on this</p> <p>19 picture.</p> <p>20 Q. I didn't ask that. I'm asking are those</p> <p>21 nerves?</p> <p>22 A. I'm not sure they are nerve or not, because</p> <p>23 based on these pictures, this particular picture.</p> <p>24 Q. So you cannot tell whether those are nerves or</p> <p>25 not?</p>	<p>1 this could be nerve. However, in the same --</p> <p>2 (By Ms. Thompson)</p> <p>3 Q. I don't want -- I want it circled. Circle</p> <p>4 that structure we were talking about and tell me is that</p> <p>5 a nerve or is that not a nerve.</p> <p>6 A. Could be nerve.</p> <p>7 Q. So the best you can do is could be nerve?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Put could be nerve but not necessarily.</p> <p>10 A. That's right.</p> <p>11 THE COURT REPORTER: Is that Dr.</p> <p>12 Iakovlev's report he's writing on?</p> <p>13 MR. SNELL: No. That's Andy's report.</p> <p>14 THE COURT REPORTER: Yeah. But it's not</p> <p>15 marked.</p> <p>16 MS. THOMPSON: Oh. We need to do it on</p> <p>17 this. Circle this and put the same thing. It's getting</p> <p>18 late.</p> <p>19 (Marked for Identification:</p> <p>20 Deposition Exhibit No. 26)</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. Okay. I'm going to hand you Exhibit 26, which</p> <p>23 is the lower panel on page 67. And how would you</p> <p>24 describe that?</p> <p>25 MR. SNELL: Do you have a copy?</p>
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<p>1 A. Again, if I want to identify nerve, then I</p> <p>2 want to see under H&E, under higher power of the</p> <p>3 microscope.</p> <p>4 Q. Did you look at this slide?</p> <p>5 A. I looked at slides.</p> <p>6 Q. Did you find this area?</p> <p>7 A. In S100 stained slides, I found this area.</p> <p>8 However, under the H&E slide, I don't see that area.</p> <p>9 Q. And in the S100 slide that you looked at, did</p> <p>10 you put it under high power?</p> <p>11 A. Yes, I did.</p> <p>12 Q. And could you identify those as nerves?</p> <p>13 A. Some of them may represent a nerve. Some of</p> <p>14 them may not.</p> <p>15 Q. So the best you can do on that is some of</p> <p>16 these may represent nerves?</p> <p>17 A. Correct.</p> <p>18 Q. So in the picture, the bottom one from your</p> <p>19 page, the nerve that's -- is elongated and twisting</p> <p>20 around the -- is that a nerve or not?</p> <p>21 A. Which picture?</p> <p>22 Q. If you just put -- mark that, circle it, and</p> <p>23 tell me is that a nerve or is that not a nerve.</p> <p>24 MR. SNELL: Form.</p> <p>25 A. Based on this particular staining, again, yes,</p>	<p>1 MS. THOMPSON: I'm sorry.</p> <p>2 A. That's S100 staining.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. And what do you see?</p> <p>5 A. I see some brown stained area and some</p> <p>6 nonstained area.</p> <p>7 Q. Are those nerves?</p> <p>8 A. This could be nerve. For this particular</p> <p>9 structure, could be nerve, yes.</p> <p>10 Q. Go ahead and circle that and say could be</p> <p>11 nerve.</p> <p>12 A. Okay. Could be nerve. That's true. However,</p> <p>13 the point Dr. Iakovlev want to point out is it says nerve</p> <p>14 degeneration. That's his point.</p> <p>15 Q. Do you disagree that that's nerve</p> <p>16 degeneration?</p> <p>17 A. I totally disagree.</p> <p>18 Q. What is it?</p> <p>19 A. Because first of all --</p> <p>20 Q. What is it? What is that structure?</p> <p>21 A. What is structure? This nonstained -- first</p> <p>22 of all, nerve degeneration belong to degenerative</p> <p>23 neurodisorder, a part of the neurodegenerative disorder.</p> <p>24 Then typically, as I stated in my report, says those</p> <p>25 conditions classically occur when you have a neuron get</p>

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1 injured. Then the peripheral part or distal part of that
2 injured neuron in these nerve may start to have
3 degenerative changes. Okay?
4 Then they are -- they will present usually
5 it's not a single focus. You will see many similar
6 pictures will be identified. All right? But for this
7 instance, I have only see single microscopic focus from
8 what Dr. Iakovlev stained. More than hundred of these
9 brown stained area or he called nerve. Okay?
10 Q. So your opinion is this could be a nerve, but
11 it's not a degenerated nerve?
12 A. No. What I said, could be nerve in the
13 outside area. In the center, what he point out in the
14 center nonstained area is degeneration. Then he said
15 because of no staining, then that's degeneration. That's
16 his conclusion, and that's the reason for his conclusion.
17 But I disagree for that.
18 Q. So it's not degenerated?
19 A. I don't think this represent degenerated
20 nerve, number one.
21 Q. Are you saying --
22 A. Number two is these single clusters it's also
23 not necessary saying this is a single nerve. You
24 understand?
25 Q. How many slides did you stain?

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1 A. For me? Stained for neurofilaments?
2 Q. How many slides?
3 A. One block -- one slide each from each block.
4 Q. Two sides?
5 A. Two slides.
6 Q. And you could have stained many more had you
7 chosen to, correct?
8 MR. SNELL: Foundation.
9 A. I have no reason why I need to stain a lot
10 more.
11 (By Ms. Thompson)
12 Q. So it's really not fair to say you only saw
13 one nerve when you didn't look at anything more than two
14 sections?
15 A. No. Because he stained four slides. Okay?
16 Duplicate from each block, two of them, all right?
17 That's plenty.
18 Then, however, let me emphasis why this is
19 so isolated focus. Because from the same block different
20 level, then I am not able to find the same thing like
21 this, number one.
22 Number two, within all these two blocks,
23 two slides -- or four slides stained, only one area like
24 this. Therefore, it's very isolated conditions. All
25 right? This is very common in Dr. Iakovlev's report. He

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1 use all these single identification or pictures then to
2 generalize his conclusion.
3 Q. Are you saying that mesh cannot cause nerves
4 to be damaged or degenerate?
5 A. At least I don't see such evidence.
6 Q. Do you not see such evidence in any of the
7 meshes you've examined, or do you not see the evidence in
8 Ms. Edwards?
9 A. I see -- not only Edwards. In all the
10 specimens I have examined in the past three years.
11 Q. So would you also say -- if your opinion is
12 that that's not degenerated, put that on there, also.
13 A. What I said here, I say this picture does not
14 represent central nerve degradation.
15 (Marked for Identification:
16 Deposition Exhibit No. 27)
17 (By Ms. Thompson)
18 Q. This is page 68. I've marked this as
19 Exhibit 27. And I want for you to identify for me what
20 is this blue area here?
21 MR. SNELL: Can I have a copy, please?
22 Which blue area are you talking about?
23 THE WITNESS: These blue granules.
24 A. Based on my understanding by reading through
25 his reports, he --

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1 (By Ms. Thompson)
2 Q. I'm just asking you, what is that? If you
3 look at that, what is the blue staining or the blue area
4 here?
5 A. Right. The question is very limited. If I
6 don't know the context, I can't --
7 Q. But you do know the context, right? It's from
8 Tonya Edwards. So what is that blue?
9 A. So based on the context for this case, this
10 area was taken from the mesh, represent the mesh fibers.
11 Q. Do blue granules appear anywhere in the human
12 body naturally?
13 A. Blue granules, when you blow up into very high
14 resolution or magnifications, yes, you can see even blue
15 granule-like appearance will be even in the collagen.
16 Q. I think my question was, do blue granules --
17 not a blue granular appearance -- do blue granules occur
18 anywhere in the human body?
19 MR. SNELL: Objection. Asked and
20 answered.
21 Go ahead and tell her.
22 A. This is synthetic material. Therefore, normal
23 human tissue will not have such a synthetic material.
24 (By Ms. Thompson)
25 Q. Okay. That was my only question.

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<p>1 And then what is here?</p> <p>2 A. That is part of the connective tissue or</p> <p>3 incorporated tissue, tissue integrated into the --</p> <p>4 adjacent to the mesh.</p> <p>5 Q. So let's go ahead and mark with the Sharpie</p> <p>6 the blue granule area as -- that can just be TVT-O or PP,</p> <p>7 whatever you want to say that is.</p> <p>8 A. You mean this?</p> <p>9 Q. Label that.</p> <p>10 A. Just say mesh fiber.</p> <p>11 Q. Okay. And then label the connective tissue or</p> <p>12 however you want to label the other portion.</p> <p>13 And then I want you to tell me not what</p> <p>14 Dr. Iakovlev thinks this is, but what you think this rim</p> <p>15 is there.</p> <p>16 A. When you -- when a picture blow into such high</p> <p>17 conditions, it's very difficult to say what is this.</p> <p>18 First of all, it shows different color. Like, for</p> <p>19 instance, like in the relatively lower power in the same</p> <p>20 picture in the upper panel, it shows purple blue in outer</p> <p>21 layer, and then inner layer represent mesh fiber.</p> <p>22 Q. Okay. I don't believe you answered my</p> <p>23 question. What do you think that rim represents? What</p> <p>24 is it composed of?</p> <p>25 A. That could be degenerated collagen.</p>	<p>1 even don't recognize this is your own face. The same</p> <p>2 situation happens. All right?</p> <p>3 Q. Did you look at this area of Tonya Edwards'</p> <p>4 slide yourself?</p> <p>5 A. Yes, I looked.</p> <p>6 Q. And did you put it on a lower power to try to</p> <p>7 appreciate the appearance?</p> <p>8 A. I even created pictures for that.</p> <p>9 Q. So back to your opinion that this is</p> <p>10 degenerated collagen.</p> <p>11 MR. SNELL: Do you want him to show you</p> <p>12 the pictures?</p> <p>13 MS. THOMPSON: No. I didn't ask for those</p> <p>14 pictures.</p> <p>15 MR. SNELL: All right.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. Then -- so, in your opinion, that represents</p> <p>18 degenerated collagen, correct? And the blue granules</p> <p>19 that are in that rim that you're representing in your</p> <p>20 opinion is degenerated collagen are a function of levels</p> <p>21 of sectioning, correct, superimposed?</p> <p>22 A. Could be, yes.</p> <p>23 Q. And you had hundreds of sections that you</p> <p>24 could do off the block that you had to satisfy yourself</p> <p>25 as to whether that's really what they represented or not,</p>
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<p>1 Q. Okay. What else could it be?</p> <p>2 A. I think my answer probably -- that will be</p> <p>3 just a reasonable answer.</p> <p>4 Q. So that's the only possibility that that could</p> <p>5 be is degenerated collagen?</p> <p>6 A. Degenerated collagen is a better answer than</p> <p>7 says these are degenerated mesh fibers.</p> <p>8 Q. How do you explain blue granules in</p> <p>9 degenerated collagen?</p> <p>10 MR. SNELL: Form. Foundation. Misstates.</p> <p>11 MS. THOMPSON: Well, okay. All right.</p> <p>12 MR. SNELL: Because he told you that he</p> <p>13 doesn't think they're blue granules. He told you that</p> <p>14 five minutes ago.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. Okay. Let's look -- you don't think those are</p> <p>17 blue granules in the polypropylene fiber there?</p> <p>18 A. Let me actually explain to you. These blue</p> <p>19 granules, even under -- or just superimposed with these</p> <p>20 purple color does not necessarily say these granules are</p> <p>21 within this purple color. They can be just superimposed</p> <p>22 in a different plane. Because when you magnify very</p> <p>23 small tiny area to such a big thing, then things change.</p> <p>24 I can tell you, give you a scenario. If</p> <p>25 you blow out your face to a very large area, then you</p>	<p>1 correct?</p> <p>2 MR. SNELL: Foundation.</p> <p>3 A. As I said, it's better for me to examine the</p> <p>4 same slides as the plaintiffs' side expert. Then we are</p> <p>5 talking to the same thing. If I further section many</p> <p>6 sections, then present some pictures, he may never see.</p> <p>7 Then we end up backward and forward, you know, talking --</p> <p>8 not talking to the same thing.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. But if the expert that you're criticizing says</p> <p>11 that the blue granules are in the rim and you have the</p> <p>12 ability to confirm whether or not that's true by doing</p> <p>13 more sections, why would you not do that?</p> <p>14 A. Because there is no reason for me to try to</p> <p>15 show these granules, because I think these granules are</p> <p>16 irrelevant, number one. All right? Overall you see,</p> <p>17 under reasonable power or lower power, you can see those</p> <p>18 mesh spaces all over the place, very clear. And then we</p> <p>19 do have a bark-like area in the many areas.</p> <p>20 Q. Yes, we do because --</p> <p>21 A. Yes, right.</p> <p>22 Q. -- the polypropylene is degraded in many</p> <p>23 areas, correct?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. No, that's not correct. Because -- yes, we</p>

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1 do, because the collagen bundles or extracellular matrix
 2 have to be densely adhered to the mesh fibers then to
 3 support or to secure the mesh is within the tissue.
 4 Q. Okay. Let's go back to the blue granules.
 5 A. Okay.
 6 Q. You would agree with me that blue granules
 7 that are put in TVT mesh for coloration -- you agree with
 8 me that TVT mesh contains blue granules that are placed
 9 for coloration, correct?
 10 A. TVT mesh fiber, one monofilament is used blue
 11 color, that's true.
 12 Q. Okay. And that is done with blue granules in
 13 the mesh?
 14 A. Then if you magnify, everything become
 15 granule. That's true.
 16 Q. All right. The mesh -- somehow TVT mesh is
 17 colored blue. Okay. That's just leave it at that.
 18 Right, it's blue?
 19 A. Yes.
 20 Q. Okay. We know that because I tried to bring
 21 my mesh out earlier.
 22 A. Right.
 23 Q. And Mr. Snell didn't let me go very far with
 24 it.
 25 So TVT mesh is blue. Is there any

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1 situation that you can think of that blue granules would
 2 appear in collagen?
 3 Any situation, not -- we're not even
 4 talking about Tonya Edwards. Some situation where blue
 5 granules, not a blue-colored cell, but blue granules,
 6 synthetic material, would appear in collagen?
 7 MR. SNELL: You mean beyond what he has
 8 already told you?
 9 A. As I said, I don't believe --
 10 (By Ms. Thompson)
 11 Q. That's not a sectioning. It's actually in the
 12 collagen.
 13 A. I don't believe --
 14 MR. SNELL: Not in a photograph? In the
 15 collagen?
 16 MS. THOMPSON: In the collagen.
 17 (By Ms. Thompson)
 18 Q. Is there a situation where blue granules could
 19 occur in collagen?
 20 A. Yeah. If you have the sectioning. For
 21 instance --
 22 MR. SNELL: Form.
 23 (By Ms. Thompson)
 24 Q. Not sectioning. Is there a situation in the
 25 human body where blue granules could appear in collagen?

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1 MR. SNELL: Form.
 2 A. I'm not aware of any situation like this.
 3 (By Ms. Thompson)
 4 Q. Okay. And your contention is that the
 5 appearance of the blue granules in this rim that you
 6 believe is collagen is a function of the sectioning
 7 technique, right? I think that's what you said.
 8 A. It's -- they may represent in a different
 9 plane, that's true.
 10 Q. A different plane?
 11 A. A different plane. It's not like section --
 12 because of section-induced artifact.
 13 Q. Not artifact. They're cut in a different
 14 plane?
 15 A. Right.
 16 Q. So you have granules superimposed on top of
 17 this rim because it's impossible all the time to get it
 18 exactly straight. Is that what you're saying?
 19 A. Correct. Okay. And then --
 20 Q. And you had the opportunity to look at
 21 hundreds of more sections to see if these granules are
 22 actually in what you think is degraded, degenerated
 23 collagen or whether they're not, and you didn't do that.
 24 And I'm just trying to understand why.
 25 So why did you -- if you could prove that,

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1 your theory that this was done by -- because the blue
 2 granules are a different plane, why didn't you do that?
 3 Why didn't you take more sections?
 4 MR. SNELL: Form, foundation. He's
 5 already answered this three times.
 6 Go ahead.
 7 A. Because there is no reason.
 8 (By Ms. Thompson)
 9 Q. Because they're irrelevant? Is that --
 10 A. For me, this is totally irrelevant.
 11 Q. Okay. All right.
 12 A. Okay?
 13 Q. And you weren't curious as to what you would
 14 see if you did more sections?
 15 A. Because I have so many such bark-like area,
 16 why I need to do more? Therefore, I take many
 17 sections -- many pictures to show these material are, you
 18 know, present in many places.
 19 (Marked for Identification:
 20 Deposition Exhibit No. 28)
 21 (By Ms. Thompson)
 22 Q. Okay. Let's just take one of yours and mark
 23 it. And I really don't need you to do anything with this
 24 other than to have to show that you have a bark-like
 25 appearance in each of those areas where the polypropylene

<p style="text-align: right;">Page 246</p> <p>1 fiber was, correct?</p> <p>2 A. Right. I labeled them very clearly. I say,</p> <p>3 The "bark" like areas are squared under the regular</p> <p>4 microscopy.</p> <p>5 MR. SNELL: For the record, it's, quote,</p> <p>6 bark, close quote.</p> <p>7 THE WITNESS: Right. That's his word.</p> <p>8 Actually the bark -- so-called bark, this is the first</p> <p>9 time I heard bark, which has never been, you know, used</p> <p>10 in the pathology book.</p> <p>11 MS. THOMPSON: I do not think Dr. Iakovlev</p> <p>12 would have any problem with putting that in quotations.</p> <p>13 (Marked for Identification:</p> <p>14 Deposition Exhibit No. 29)</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. I've just marked Exhibit 29, which is on page</p> <p>17 43. And I believe this is an area similar to what we</p> <p>18 were looking at before, correct?</p> <p>19 A. Correct.</p> <p>20 Q. And on the left-hand side, let's do the same</p> <p>21 thing. Will you write on that what the blue-colored area</p> <p>22 represents.</p> <p>23 Mesh fiber, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And what about the pink-colored area in the --</p>	<p style="text-align: right;">Page 248</p> <p>1 of fibrosis is from this magnification?</p> <p>2 A. Right. From this particular picture it's not</p> <p>3 reasonable to say so certain. People will laugh. In the</p> <p>4 professional level, we have to follow our professional</p> <p>5 practice.</p> <p>6 Q. But I think you can say that that is not loose</p> <p>7 connective tissue, correct?</p> <p>8 A. Yeah. It's integrated tissue.</p> <p>9 Q. Okay. Well, that wasn't my question. You</p> <p>10 can't say that that's not loose connective tissue,</p> <p>11 correct?</p> <p>12 MR. SNELL: Form.</p> <p>13 A. It's not loose connective tissue.</p> <p>14 (By Ms. Thompson)</p> <p>15 Q. And then I want you to tell me what this area</p> <p>16 that you drew the line to, what that represents?</p> <p>17 And go ahead and read what you wrote.</p> <p>18 A. I wrote, said, Most likely this represent</p> <p>19 collagen bundles densely adhered to the mesh fiber.</p> <p>20 Q. Okay. Now, that collagen doesn't look like</p> <p>21 the collagen adjacent to it, does it?</p> <p>22 A. Correct. Because it's densely adhered to the</p> <p>23 mesh fiber. Therefore, it has less chance to be -- to</p> <p>24 get or to obtain any nutrition from blood supply.</p> <p>25 Q. So this is degenerated collagen?</p>
<p style="text-align: right;">Page 247</p> <p>1 no, no. The other one. The pink -- the bright -- the</p> <p>2 pink at the bottom, what is that?</p> <p>3 A. Integrated tissue.</p> <p>4 Q. So that's connective tissue?</p> <p>5 A. Yes.</p> <p>6 Q. And would you call that loose connective</p> <p>7 tissue?</p> <p>8 A. This is relatively dense.</p> <p>9 Q. So that -- why don't we put dense connective</p> <p>10 tissue there.</p> <p>11 MR. SNELL: How about we put relatively</p> <p>12 dense, what his words were, if you want to put it on</p> <p>13 there.</p> <p>14 MS. THOMPSON: That's fine.</p> <p>15 A. It's integrated tissue. There's no reason to</p> <p>16 tell the difference between loose and dense.</p> <p>17 (By Ms. Thompson)</p> <p>18 Q. Then let's do your mild to moderate, marked</p> <p>19 fibrosis.</p> <p>20 A. Because --</p> <p>21 Q. Is that mild, moderate or marked fibrosis?</p> <p>22 A. As I said, this is very magnified area in a</p> <p>23 small corner. If you want to see like fibrosis, then,</p> <p>24 yeah, use those pictures.</p> <p>25 Q. Okay. So you can't determine what the level</p>	<p style="text-align: right;">Page 249</p> <p>1 A. Most likely these densely adhered to those</p> <p>2 area represent degenerated collagen.</p> <p>3 Q. And there's nothing else that you would</p> <p>4 entertain that that could be?</p> <p>5 A. At least this does not look like mesh fiber or</p> <p>6 degraded mesh fiber, because if it's a true degraded mesh</p> <p>7 fiber, then you should partially, in like polarization</p> <p>8 condition or regular microscope, showing similar blue</p> <p>9 granules inside. Right?</p> <p>10 Q. What, to you, what are these -- what is this</p> <p>11 blue area here on the border of what you think is</p> <p>12 degenerated collagen that's the same color as your mesh</p> <p>13 fiber?</p> <p>14 MR. SNELL: Foundation, same color.</p> <p>15 MS. THOMPSON: I'm color blind. What do I</p> <p>16 know?</p> <p>17 A. That's why when you magnify to very high</p> <p>18 magnification, then all these pictures you really don't</p> <p>19 know from the visual point of view what are they. You</p> <p>20 understand, right? Because you are pinpointed to ask me</p> <p>21 less than a micron level, you know, color represent what?</p> <p>22 I don't think anybody in this world is able to give you</p> <p>23 answer like this.</p> <p>24 (Marked for Identification:</p> <p>25 Deposition Exhibit No. 30)</p>

<p style="text-align: right;">Page 250</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. Okay. And would you say the same with this</p> <p>3 next one that I'll mark as Exhibit 30?</p> <p>4 A. That one even -- can you tell me how much</p> <p>5 magnification that is? This one magnified to?</p> <p>6 Q. So you disagree that those are blue granules</p> <p>7 in your degenerated collagen?</p> <p>8 MR. SNELL: Foundation.</p> <p>9 (By Ms. Thompson)</p> <p>10 Q. In your opinion, that's not even possible?</p> <p>11 A. Right. Because you see -- if you see a few</p> <p>12 like blue granules, what are they? All right?</p> <p>13 Q. That's my question.</p> <p>14 A. Right. What are they? Then you can ask him.</p> <p>15 He said these are, you know, degraded mesh. Then I say</p> <p>16 this is not. Okay. So who is right? Who is wrong?</p> <p>17 Nobody knows.</p> <p>18 Q. Does collagen --</p> <p>19 A. Because when we are using common sense -- and,</p> <p>20 plus, this is not general surgical pathology practice.</p> <p>21 Right?</p> <p>22 Q. Does collagen polarize bright purple like is</p> <p>23 in that picture?</p> <p>24 A. Collagen can be -- yes, can be like similar to</p> <p>25 the purple color.</p>	<p style="text-align: right;">Page 252</p> <p>1 MS. THOMPSON: I'm just going to mark it</p> <p>2 as an exhibit.</p> <p>3 THE WITNESS: Yeah. Sure.</p> <p>4 (Marked for Identification:</p> <p>5 Deposition Exhibit No. 31)</p> <p>6 THE WITNESS: Let me explain to you.</p> <p>7 (By Ms. Thompson)</p> <p>8 Q. I want you to mark on it with your pen where</p> <p>9 is the polarized collagen?</p> <p>10 A. Hold on. I have to explain one by one.</p> <p>11 Q. I am just asking for one thing, and that's</p> <p>12 mark the polarized collagen.</p> <p>13 A. I know, but you have to go step by step.</p> <p>14 Q. Well, I don't really have time, and I get to</p> <p>15 choose what I want, unfortunately, what I want to talk</p> <p>16 about. And I want you to mark the polarized collagen,</p> <p>17 please.</p> <p>18 A. Then I have another picture. That's why you</p> <p>19 need --</p> <p>20 Q. Is there any collagen that's polarizing on</p> <p>21 this picture?</p> <p>22 A. There is no, no polarized -- collagen is not</p> <p>23 polarized, collagen before polarization. After</p> <p>24 polarization they show the same color. Okay? Number</p> <p>25 one. Because this is a routine microscope before and</p>
<p style="text-align: right;">Page 251</p> <p>1 Q. Do you see collagen that polarizes like this?</p> <p>2 A. I did not magnify to this level, but I do have</p> <p>3 a picture showing collagen -- true collagen, because</p> <p>4 that's in the connective tissue. It's away from the</p> <p>5 polypropylene mesh.</p> <p>6 Q. Did you use the polarizer when you were</p> <p>7 looking at these slides?</p> <p>8 A. Yes.</p> <p>9 Q. Can you show me ones that you polarized and</p> <p>10 where the collagen is showing up?</p> <p>11 A. Okay. So for instance --</p> <p>12 MR. SNELL: Hold on. She's asking you to</p> <p>13 show us. Take your time.</p> <p>14 He has a whole section on polarized.</p> <p>15 So give them to her.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. I want you to show me -- I just want to see</p> <p>18 one thing, and that's the polarization of collagen in a</p> <p>19 picture that you have brought.</p> <p>20 A. Okay. First of all I show you this picture.</p> <p>21 All right? This picture let me explain to you. So this</p> <p>22 is the regular microscope. Okay? And this is the</p> <p>23 polarized condition. You got it? And then this is the</p> <p>24 polarized condition when we have a mesh fiber like this.</p> <p>25 See this? Hold on.</p>	<p style="text-align: right;">Page 253</p> <p>1 after polarization to compare.</p> <p>2 Q. Okay. I would like to see the picture where</p> <p>3 you have the polarized -- polarization of the collagen</p> <p>4 that you take a picture of the polarized collagen.</p> <p>5 A. Okay. We have this picture. This is</p> <p>6 so-called bark-like area. Okay? It's purple. Right?</p> <p>7 Similar to what Dr. Iakovlev showed, but this is</p> <p>8 magnified to almost a hundred at least. Or let's see.</p> <p>9 Maybe 600, something like that, magnification.</p> <p>10 Then this is the polarized. These area is</p> <p>11 connective tissue. It's clear. Right? There's no mesh</p> <p>12 fiber material. You see? After polarization, these</p> <p>13 area -- see these blue color? Right? If you look very</p> <p>14 carefully or blow into that kind of level, you also see</p> <p>15 blue granules. Then these blue colors basically</p> <p>16 identical to these bark-like area. You see that blue</p> <p>17 color?</p> <p>18 Q. You're telling me that this -- these blue</p> <p>19 cellular areas are the same as this --</p> <p>20 A. Correct.</p> <p>21 Q. -- blue bark?</p> <p>22 A. Right. These are polarized.</p> <p>23 Q. Would you say that -- would you write on</p> <p>24 here -- point to this, this here, and say that this is</p> <p>25 the same as whatever is there that you think is the same.</p>

<p style="text-align: right;">Page 254</p> <p>1 Circle what's the same here and what's the same there.</p> <p>2 A. I already --</p> <p>3 MR. SNELL: It's already on there.</p> <p>4 There's a whole legend on there.</p> <p>5 MS. THOMPSON: I don't care about his</p> <p>6 legend. I want him to write down with a Sharpie that</p> <p>7 this is the same as what area there that you're saying it</p> <p>8 is the same as.</p> <p>9 MR. SNELL: Just put "same" on there,</p> <p>10 because it says it already.</p> <p>11 (By Ms. Thompson)</p> <p>12 Q. No. I want you to circle the part that's the</p> <p>13 same, please.</p> <p>14 A. There's so many I have those. My God.</p> <p>15 Q. Okay. Well, we're talking about a continuous</p> <p>16 rim, and you're picking out little isolated blue areas.</p> <p>17 Is that what you're saying is the same?</p> <p>18 A. Yeah.</p> <p>19 Q. Okay.</p> <p>20 A. Do you want to mark your exhibits before we go</p> <p>21 further and we forget?</p> <p>22 (Marked for Identification:</p> <p>23 Deposition Exhibit No. 32)</p> <p>24 (Marked for Identification:</p> <p>25 Deposition Exhibit No. 33)</p>	<p style="text-align: right;">Page 256</p> <p>1 then the color should be similarly to the nondegraded</p> <p>2 area in certain part. Particularly under polarized</p> <p>3 conditions you can see better. However, with my own</p> <p>4 polarized observation, I do not see that, number one.</p> <p>5 Number two, if it's truly representing</p> <p>6 degraded outer layer of the mesh fiber, then we should</p> <p>7 see -- usually we should see like irregular borders</p> <p>8 between the degraded area and nondegraded area.</p> <p>9 However, in majority of the situation, we</p> <p>10 see clear-cut kind of bark layer, very clear. All right?</p> <p>11 But except you magnify to more than -- you know, very</p> <p>12 high magnification, then you see sort of granular</p> <p>13 appearance. Okay?</p> <p>14 Q. I will represent --</p> <p>15 A. So those are the evidence for me. Plus, those</p> <p>16 similar polarized condition versus nonpolarized</p> <p>17 condition, they more likely represent to those extra</p> <p>18 cellular matrix such as collagen. Because it's densely</p> <p>19 adhered to the mesh fiber, then they change their</p> <p>20 original property. Therefore, it's reasonable to say</p> <p>21 it's more likely those area represent degenerated</p> <p>22 collagen.</p> <p>23 Q. But it's possible that it's degraded</p> <p>24 polypropylene?</p> <p>25 MR. SNELL: Form.</p>
<p style="text-align: right;">Page 255</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. And would you also write on this one, No</p> <p>3 polarized collagen.</p> <p>4 A. That's within my legend.</p> <p>5 Q. I just want you to write it, please.</p> <p>6 MR. SNELL: Just write it at the bottom</p> <p>7 and try not to mess up your pictures too much.</p> <p>8 MS. THOMPSON: We're going to have to</p> <p>9 break for the video.</p> <p>10 MR. SNELL: Okay.</p> <p>11 THE VIDEOGRAPHER: Off the record 6:55.</p> <p>12 This concludes tape number five.</p> <p>13 (Recess taken.)</p> <p>14 THE VIDEOGRAPHER: On the record 7:14.</p> <p>15 This begins tape number six.</p> <p>16 (By Ms. Thompson)</p> <p>17 Q. Dr. Zheng, you are one hundred percent sure</p> <p>18 that the, in quotations, bark that we've been looking at</p> <p>19 is not degraded polypropylene? Is that what you're</p> <p>20 telling me today?</p> <p>21 A. I should say nobody can say one hundred</p> <p>22 percent sure, because that statement is not right. And I</p> <p>23 said most likely this does not look like degraded mesh</p> <p>24 fiber or part of the mesh fiber for multiple reasons.</p> <p>25 For instance, if it's degraded mesh fiber,</p>	<p style="text-align: right;">Page 257</p> <p>1 A. That's what I already said. It's more likely.</p> <p>2 I did not say one hundred percent.</p> <p>3 (By Ms. Thompson)</p> <p>4 Q. What are -- can you think of anything else it</p> <p>5 could be besides degenerated collagen and degraded</p> <p>6 polypropylene?</p> <p>7 A. From a pathologist's point of view, I don't</p> <p>8 think any other choices.</p> <p>9 Q. So those are the only two choices?</p> <p>10 A. Two potential choices, but I favor my</p> <p>11 interpretation.</p> <p>12 Q. And if there were truly blue granules inside</p> <p>13 the bark, not in a different plane superimposed on the</p> <p>14 bark, would that persuade you that it would be more</p> <p>15 likely degraded polypropylene than what you think now?</p> <p>16 A. No. That will not change my opinion, because</p> <p>17 those -- you see we are talking about like one micron</p> <p>18 kind of level, one to two micron level in this situation.</p> <p>19 When it densely adhere to something in molecular levels</p> <p>20 or close to molecular levels, those small particles</p> <p>21 coming off that's easy to see. Therefore, you know,</p> <p>22 there is no way to prove one way or the other.</p> <p>23 (Marked for Identification:</p> <p>24 Deposition Exhibit No. 35)</p> <p>25</p>

<p style="text-align: right;">Page 258</p> <p>1 (By Ms. Thompson)</p> <p>2 Q. I've marked as Exhibit 35 a scanning EM of</p> <p>3 polypropylene filament. What do you see in this picture?</p> <p>4 This is on -- it's a much better picture</p> <p>5 if you look at Dr. Iakovlev's report on page 45.</p> <p>6 A. That's a transmission electron microscopy.</p> <p>7 Q. That's right. It's a TEM. If I said</p> <p>8 scanning, I meant to say TEM.</p> <p>9 And do you disagree that this is</p> <p>10 indicative of surface changes on the polypropylene?</p> <p>11 MR. SNELL: I want to put an objection on</p> <p>12 the record. This Figure 25, the legends aren't included</p> <p>13 on any of these. This states, Specimen of an explanted</p> <p>14 transvaginal sling of another brand, et cetera. So I</p> <p>15 want to make sure the record is clear this isn't Edwards.</p> <p>16 A. In addition to that, I can assure you I'm not</p> <p>17 the expert for electron microscope to interpret things.</p> <p>18 Therefore, I don't have any opinion how to comment on</p> <p>19 this.</p> <p>20 (By Ms. Thompson)</p> <p>21 Q. Okay. So you will not be testifying at trial</p> <p>22 as to the findings on any transmission or scanning</p> <p>23 electron microscope?</p> <p>24 A. Correct. Because that's not in my training</p> <p>25 expertise.</p>	<p style="text-align: right;">Page 260</p> <p>1 MS. THOMPSON: If you'll turn to page 40.</p> <p>2 THE COURT REPORTER: Are you marking them</p> <p>3 out of sequence now?</p> <p>4 MS. THOMPSON: Oh, was that not the right</p> <p>5 number?</p> <p>6 THE COURT REPORTER: Well, you marked a</p> <p>7 couple. Are you not going to use those? I'll give you</p> <p>8 stickers so they can be --</p> <p>9 MS. THOMPSON: I just -- this is 38.</p> <p>10 THE COURT REPORTER: You've got 36 and 37</p> <p>11 that you're not going to use. I'll give you -- it's</p> <p>12 going to look funny if --</p> <p>13 MS. THOMPSON: Oh, you're right. Give me</p> <p>14 another one. I decided not to use those.</p> <p>15 THE COURT REPORTER: Okay. So just</p> <p>16 scribble those off so you don't think they're the</p> <p>17 originals.</p> <p>18 MS. THOMPSON: Yeah, I just need a new</p> <p>19 one. So this will be 36. Thanks for bringing that to</p> <p>20 my attention.</p> <p>21 (Marked for Identification:</p> <p>22 Deposition Exhibit No. 36)</p> <p>23 (By Ms. Thompson)</p> <p>24 Q. What does it mean when you have -- well, what</p> <p>25 do you see in these photomicrographs, as a pathologist?</p>
<p style="text-align: right;">Page 259</p> <p>1 Q. If you --</p> <p>2 A. But I can make a comment about this, because</p> <p>3 when all these small things magnify to very high levels,</p> <p>4 then the findings have to be correlated to the biological</p> <p>5 overall function or clinical performance. Then that will</p> <p>6 be meaningful. Otherwise we are talking about like one</p> <p>7 thing is on Mars, the other thing is on Earth. It's</p> <p>8 totally two different things.</p> <p>9 Q. Well, isn't the whole purpose of scanning EM</p> <p>10 to magnify above and beyond what you can do with a light</p> <p>11 microscope?</p> <p>12 A. Because anything magnified to very high</p> <p>13 levels, then you show the picture, those pictures are</p> <p>14 usually they are not representative for real life,</p> <p>15 because it's too small area. You understand, right?</p> <p>16 Q. So you're saying --</p> <p>17 A. What I'm saying is very tiny area, if you have</p> <p>18 some changes, then so what? Right? Because overall you</p> <p>19 need to see these mesh within the place, in vivo</p> <p>20 condition, to see the function to reduce the SUI. That's</p> <p>21 the purpose.</p> <p>22 Q. So would you say that a scanning micrograph</p> <p>23 showing mesh degradation would be irrelevant to you?</p> <p>24 A. It's totally irrelevant. Plus, this is not</p> <p>25 published material, also.</p>	<p style="text-align: right;">Page 261</p> <p>1 A. For Figure 22?</p> <p>2 Q. Yeah. Let's start with Figure 22.</p> <p>3 A. Figure 22 he stated as immunoglobulin</p> <p>4 distribution. Basically he stains with</p> <p>5 immunohistochemical method, stained with immunoglobulin</p> <p>6 antibody to identify immunoglobulin.</p> <p>7 Q. And what does that signify, the staining that</p> <p>8 you see in this picture?</p> <p>9 A. Some brown area, some nonstained area, and</p> <p>10 that's it.</p> <p>11 Q. And do you agree that the bark does not</p> <p>12 contain a detectable concentration of IgG?</p> <p>13 A. I'm not sure even this area which -- if this</p> <p>14 is the area -- let me show you are we talking about same</p> <p>15 thing. This area if he said is a bark because this one</p> <p>16 is closely associated with the mesh, right? Then this</p> <p>17 area shows lots of staining there.</p> <p>18 Q. Does the myeloperoxidase stain indicate</p> <p>19 oxidation?</p> <p>20 A. No. The 22, we are talking about</p> <p>21 immunoglobulin staining.</p> <p>22 Q. Okay. Let's go to the myeloperoxidase, 23.</p> <p>23 A. Okay. Right. Then myeloperoxidase staining</p> <p>24 typically stains many inflammatory cells. Okay? Or some</p> <p>25 of these living cells. Then they have myeloperoxidase.</p>

<p style="text-align: right;">Page 262</p> <p>1 Q. And that means that they are actively working, 2 phagocytizing or -- 3 A. Phagocytizing. 4 MR. SNELL: Form. 5 A. It's not necessary saying that, because, you 6 know, that basically indicating the presence of 7 inflammatory cells or macrophages or like foreign body 8 giant cells. 9 (By Ms. Thompson) 10 Q. And would you agree that the bark does not 11 pick up the myeloperoxidase stain? 12 A. From this area, what he showed, the area 13 actually in the up little bit of corner. You see the 14 corner in the middle of this area? You have some 15 staining there, too. See that? Can you see that 16 clearly? 17 Q. Where the bark is? 18 A. Yeah, where he called the bark. Then you see 19 the stained area. 20 Q. You need to write on this. 21 And collagen stains positive for 22 myeloperoxidase; is that right? 23 A. No. Pure collagen will not. 24 Q. The cells? 25 A. The cells, part of the cellular component may</p>	<p style="text-align: right;">Page 264</p> <p>1 A. I feel -- originally I try to repeat his S100, 2 for instance, number one. Number two, like inflammatory 3 cells, CD45 staining. Then after when I examined those 4 neurofilament staining sections, I noticed these sections 5 already fragmented. So I'm afraid if I keep cutting, one 6 is may exhaust the material. There is a risk there. And 7 two is all these fragmented tissue may not give me any 8 good results anyway. So, therefore, I don't need to do 9 that. And, plus, he has provided lots of slides already. 10 Q. Okay. So you had what you needed, in your 11 opinion? 12 A. I think my additional concern is my comments 13 should be the same picture or same slides he is using. 14 That will be better, because we are talking the same 15 thing. Otherwise another argument coming. Says, okay, 16 we are talking about different level, different things. 17 Q. So even though you contradicted him and could 18 have proven your position with more sections, you chose 19 not to do that; is that correct? 20 MR. SNELL: Form. 21 Go ahead. 22 A. I think it's better to just use the 23 information he used. Then we're talking about the same 24 thing. 25</p>
<p style="text-align: right;">Page 263</p> <p>1 stain, depending on if they have that particular antigen 2 there. 3 Q. Okay. So you have one spot identified which 4 actually looks to me like it's attached to tissue? 5 A. Right. 6 Q. But the remainder of what we would call the 7 bark does not have any stain, correct? 8 A. Correct. But meanwhile I want to point out in 9 the lower power, the same picture in the lower power. 10 See that? Then we have many areas stained, many area 11 nonstained. Do you see that? 12 So, therefore, this overall picture is 13 very -- basically does not mean anything. 14 Q. So you're saying the myeloperoxidase stain 15 doesn't mean anything? 16 A. Right. It's a junk stain. 17 Q. Okay. And I guess is that why you chose not 18 to do myeloperoxidase staining? 19 A. Right. Because it's meaningless. 20 Q. So you did your two neurofilament stains on 21 the blocks that you received, correct? 22 A. Correct. 23 Q. But you did not feel the need to do any 24 additional sections or any additional stains; is that 25 correct?</p>	<p style="text-align: right;">Page 265</p> <p>1 (By Ms. Thompson) 2 Q. Okay. Let's go to the last page of the 3 report. Well, it's not the last page but page 22 of your 4 report, the conclusion on Mrs. Edwards. And I know this 5 is not covering new ground, necessarily, but I want to 6 make sure I have your opinions. 7 Number one, no evidence of mesh distortion 8 is identified. Is it your testimony that any distortion 9 that appears is caused by the ex-vivo fixation process? 10 A. No. Most likely caused by so-called 11 tangential cut, random cut. 12 Q. Well, I was including that in the fixation 13 process. 14 A. Yeah. 15 Q. So any distortion apparent would be from the 16 cutting of the mesh? 17 A. Yes. Because if you read more -- large enough 18 of these sections, then you know the mesh material within 19 the tissue can show various kind of pictures. 20 Q. Okay. So that's caused by the cutting. 21 And so this gross picture that appears 22 that the mesh is curled and distorted, what's your 23 explanation for that? 24 A. That mainly -- 25 MR. SNELL: Hold on. Foundation. We</p>

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<p>1 don't know what your expert has done with it, and that's</p> <p>2 your words.</p> <p>3 A. Okay. So they're not straight --</p> <p>4 MS. THOMPSON: I asked what caused it. He</p> <p>5 can say my expert --</p> <p>6 (By Ms. Thompson)</p> <p>7 Q. What caused the apparent distortion in that</p> <p>8 photo?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 A. First of all, the specimen looks blond color,</p> <p>11 right? Blond color means the specimen has been fixed,</p> <p>12 fixed in formalin. All right? Formalin fixation will</p> <p>13 make the tissue from whitish or like bloody-looking</p> <p>14 specimens turn everything to blond.</p> <p>15 (By Ms. Thompson)</p> <p>16 Q. Okay. I'm not asking about the color. I'm</p> <p>17 asking about the distortion.</p> <p>18 A. Right. Therefore, the fixation process,</p> <p>19 formalin as we said, have two main role. One is remove</p> <p>20 the water component. After the water component removed,</p> <p>21 it will contract, tissue will contract. Okay? Number</p> <p>22 one.</p> <p>23 Number two is protein cross linking. I</p> <p>24 think Dr. Iakovlev also mentioned that. These cross</p> <p>25 linking then also will change the shape of the specimen.</p>	<p>1 entrapment of normal nerves, in your opinion?</p> <p>2 A. What do you mean? No evidence of nerve</p> <p>3 entrapment?</p> <p>4 Q. Replace the word abnormal with normal, and is</p> <p>5 that still -- would that still be your opinion?</p> <p>6 MR. SNELL: I think that's a typo,</p> <p>7 Counsel.</p> <p>8 A. Basically there's no evidence of nerve</p> <p>9 entrapment. All right? No matter what, abnormal. Then</p> <p>10 also I should say another sentence, No evidence of</p> <p>11 abnormal nerve findings.</p> <p>12 (By Ms. Thompson)</p> <p>13 Q. Okay. So there's no evidence of nerve</p> <p>14 entrapment?</p> <p>15 A. Correct.</p> <p>16 Q. Abnormal or normal nerves?</p> <p>17 A. Correct.</p> <p>18 MS. THOMPSON: I think it may be a typo,</p> <p>19 also.</p> <p>20 MR. SNELL: Yeah.</p> <p>21 (By Ms. Thompson)</p> <p>22 Q. Number six, the degree of chronic inflammation</p> <p>23 and foreign body giant cells found in this specimen is</p> <p>24 within normal limits.</p> <p>25 Are chronic inflammation and foreign body</p>
Page 267	Page 269
<p>1 One is make them harder. The other is make curve.</p> <p>2 That's for sure.</p> <p>3 Q. Okay. Number two, the specimen shows good</p> <p>4 tissue integration with mild degree of fibrosis. And</p> <p>5 that's your opinion continued, correct?</p> <p>6 A. Correct.</p> <p>7 Q. No evidence of infection or edema, but focal</p> <p>8 mesh exposure or erosion may be present. Would you say</p> <p>9 it's present to a reasonable degree of medical certainty?</p> <p>10 A. May be present. Mainly I think should be</p> <p>11 correlated to the clinical finding. If the clinician say</p> <p>12 okay or they found evidence of exposure, then that</p> <p>13 picture may go consistent with the clinical finding.</p> <p>14 Q. So you can't say still one way or another</p> <p>15 whether -- without knowing the clinical picture?</p> <p>16 A. Right. If I see clearly the fiber -- mesh</p> <p>17 fiber already sticking out of the mucosa, then that's</p> <p>18 more convincing evidence.</p> <p>19 Q. Okay. No evidence of neuroma or any kind of</p> <p>20 tumor growth found. And you're not aware that any</p> <p>21 treating doctor or expert has claimed that Ms. Edwards</p> <p>22 has a neuroma; isn't that correct?</p> <p>23 A. No.</p> <p>24 Q. You say no evidence of nerve entrapment of</p> <p>25 abnormal nerve findings. Is there any evidence of nerve</p>	<p>1 giant cells normal in the vagina?</p> <p>2 A. When any human tissues containing foreign</p> <p>3 device, then we are able to see certain amount of chronic</p> <p>4 inflammation and foreign body giant cells.</p> <p>5 Q. So you're saying it's normal if you have mesh</p> <p>6 there? You're not saying it's normal for someone who</p> <p>7 doesn't, correct?</p> <p>8 A. That's for sure.</p> <p>9 Q. Okay. That took me back a little bit.</p> <p>10 And the last one, there's no histologic</p> <p>11 evidence to support pain or dyspareunia complained by the</p> <p>12 patient.</p> <p>13 Is erosion not histologic evidence to</p> <p>14 support pain and dyspareunia?</p> <p>15 A. Usually depending on -- should be</p> <p>16 individualized, I think this is number one. And, plus,</p> <p>17 number two is I'm not sure this is truly erosion present.</p> <p>18 That's why I say it may be present.</p> <p>19 Q. Well, your statement is there is no histologic</p> <p>20 evidence. And I'm just asking, if the surgeon tells you</p> <p>21 a patient has dyspareunia and you see what looks like</p> <p>22 erosion, are you saying there's no histologic evidence to</p> <p>23 support the symptom?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. Because, as I emphasized, even the finding</p>

<p style="text-align: right;">Page 270</p> <p>1 discontinuation of the squamous mucosa in focal area, it 2 may represent erosion or exposure, right? It's not 3 confirmed yet. 4 (By Ms. Thompson) 5 Q. Okay. So you would still -- 6 A. Therefore -- plus, there is no other condition 7 such as infection or abscess formation. Then those are 8 the clear-cut evidence can cause pain. Okay? I don't 9 have those evidence at all. 10 Q. Are you saying that you have to have infection 11 or an abscess to have mesh-related dyspareunia and pain? 12 A. Yes. If I see those evidence, yes, then that 13 support pain. 14 MS. THOMPSON: I don't have any questions. 15 Do you, John? 16 MR. FABRY: No. 17 MS. THOMPSON: We're done. 18 MR. SNELL: I just have a few in 19 follow-up. 20 Dr. Zheng, just keep looking at the 21 camera. That way I don't have to come around and move 22 all your stuff. 23 EXAMINATION 24 BY MR. SNELL: 25 Q. Earlier in the deposition you were asked about</p>	<p style="text-align: right;">Page 272</p> <p>1 Smith. Hopefully they're in order over there for you. 2 A. Yes. 3 Q. This was a paper plaintiffs' counsel asked you 4 about specifically where the specimen requisition listed 5 clinical history as pain, 28.4 percent. Do you recall 6 that? 7 A. Yes, I do. 8 Q. Does this paper say that pain was actually 9 caused by the mesh? 10 A. No. Usually those study listing the reasons 11 of pain or other things based on the requisition sheet, 12 and these sheets were recorded based on the patient's 13 chief complaint. 14 Q. And does this study say that actually the 15 pathology confirmed that there was pain in 28 percent of 16 the cases, or that that was just listed on the sheet? 17 A. That's just listed on the sheet. Pathologists 18 are never be able to confirm if the patient has pain or 19 not has pain. 20 Q. You stated earlier that pain is a subjective 21 complaint; is that correct or not? 22 A. Yes. 23 Q. Does this paper discuss the number of cases 24 which were litigation-related or lawyer-referral cases? 25 A. Based on my understanding, this paper did not</p>
<p style="text-align: right;">Page 271</p> <p>1 when you began consulting with Ethicon, and I'm not sure 2 if you testified it was 2012 or 2013. 3 Do you recall the year specifically when 4 you began consulting? 5 A. Probably that's in the last year, yes. 6 Q. Okay. You were asked questions about other 7 gynecologic permanent implantable materials and whether 8 you had seen them, besides mesh. 9 My question is this: Have you seen 10 permanent sutures implanted in the gynecologic 11 application? 12 A. Yes. Sometimes we have removed tissue, 13 organs, containing suture material, that's true. 14 Q. Have you seen IUDs? 15 A. Oh, yeah. I forgot that IUD is a part of the 16 implants. 17 Q. Have you seen cervical clamps? 18 A. It's not cervical clamps. We have like 19 cerclage for cervix to prevent incompetence of the 20 cervix, like, you know, miscarriage, those situations. 21 Yes, we have those implants. 22 Then meanwhile we also have tubal 23 ligation, plastic clamp for tubal ligation. Those are 24 within the GYN field. I forgot those things. 25 Q. Turn, Doctor, to Exhibit 3. It's the paper by</p>	<p style="text-align: right;">Page 273</p> <p>1 release such information. 2 Q. At the bottom, at the end of that results 3 section, it states, No cases of neoplasm were diagnosed 4 histologically; all tissue diagnoses described benign 5 reactive processes. Do you see that? 6 A. I saw that. 7 Q. Is that consistent or inconsistent with your 8 findings? 9 A. This is consistent with my finding, too. 10 Q. And I believe plaintiffs' counsel was trying 11 to make -- or suggested that just because pain might be 12 listed on a requisition sheet in 28.4 percent of the 13 cases that one can take that generalization and apply it 14 to a particular case, such as Mrs. Huskey. 15 My question to you is, without having the 16 explant for Mrs. Huskey, can a pathologist like 17 Dr. Iakovlev scientifically and reliably opine on what 18 her tissue would show? 19 A. No. 20 MR. FABRY: Objection to form. 21 A. The answer is no. 22 (By Mr. Snell) 23 Q. And does your report explain all the reasons 24 why? 25 A. I think so I did. Because if any pathologist</p>

<p style="text-align: right;">Page 274</p> <p>1 or scientist want to make some statements, they have to</p> <p>2 have material examined. Then based on their findings,</p> <p>3 then their understandings to conclude something.</p> <p>4 Q. You were asked questions -- general</p> <p>5 questions -- strike that.</p> <p>6 You were asked general questions in the</p> <p>7 abstract whether no inflammation was better than some</p> <p>8 chronic inflammation. Do you recall those types of</p> <p>9 questions?</p> <p>10 A. Yes. But, overall, no inflammation versus</p> <p>11 mild inflammation usually translates into clinical side</p> <p>12 is to see if they are meaningful or not. Usually those</p> <p>13 conditions they are not meaningful. It shows no</p> <p>14 differences in the clinical aspects.</p> <p>15 Q. You were asked questions about Mrs. Edwards'</p> <p>16 connective tissue and it being dense or loose or these</p> <p>17 different terms.</p> <p>18 Was her connective tissue, in your</p> <p>19 opinion, normal?</p> <p>20 A. They are all belong to part of the integrated</p> <p>21 tissues.</p> <p>22 Q. Okay.</p> <p>23 A. Therefore, looks very -- reasonably normal.</p> <p>24 Q. Okay. You were asked questions about bladder</p> <p>25 perforation, and I believe you testified that you thought</p>	<p style="text-align: right;">Page 276</p> <p>1 slides produced by Dr. Iakovlev that there were missing</p> <p>2 levels. Can you explain what you meant by that?</p> <p>3 A. Mainly because, based on the slides, parallel</p> <p>4 levels, for instance, from block A or block B, they -- in</p> <p>5 the normal situation they should look very much similar</p> <p>6 from one level to the other, because only few micron</p> <p>7 away.</p> <p>8 But, however, from the slides I received,</p> <p>9 for instance either H&E or S100 staining, then one</p> <p>10 structure present in the one field, then in the next</p> <p>11 level I am not able to find those similar structure. I</p> <p>12 have to move away quite a lot.</p> <p>13 Therefore indicating there is in between,</p> <p>14 you know, multiple microns being missed. And where are</p> <p>15 they? That's usually related to tissue cutting, because</p> <p>16 the technician typically when they cut one section, then</p> <p>17 additional level, they will trim something, then go to</p> <p>18 additional level.</p> <p>19 Q. You were asked questions about how in your</p> <p>20 work you will generally look at slides, but you will also</p> <p>21 answer questions on the gross specimen if those</p> <p>22 situations arise?</p> <p>23 A. Oh, yes. Because in our academic setting,</p> <p>24 although as attending do not -- usually do not look for</p> <p>25 every gross specimens. But all the gross descriptions</p>
<p style="text-align: right;">Page 275</p> <p>1 that TVT-O had a higher rate of bladder perforation than</p> <p>2 TVT Retropubic. Do you know whether that's correct or</p> <p>3 not?</p> <p>4 A. I think I made -- my memory was wrong. TVT-O,</p> <p>5 because it's a different procedure, therefore, it's a</p> <p>6 little bit away from the bladder. Therefore, the</p> <p>7 perforation rate should be lower than the suburethra</p> <p>8 other procedures.</p> <p>9 THE WITNESS: I think I probably -- when I</p> <p>10 talked to you, that was my memory mistake.</p> <p>11 (By Mr. Snell)</p> <p>12 Q. You were asked questions about mesh</p> <p>13 complications, like exposure and inflammation. My</p> <p>14 question is, can nonmesh-related surgeries have</p> <p>15 complications like wound healing complications?</p> <p>16 A. Oh, yes. That's also any kind of surgery can</p> <p>17 have wound associated complications.</p> <p>18 Q. Can there be erosions of permanent sutures?</p> <p>19 A. There are cases reported in that way, yes.</p> <p>20 Q. Are issues like wound dehiscence, infection,</p> <p>21 inflammation specific to mesh surgery?</p> <p>22 A. I don't think so.</p> <p>23 Q. When you earlier testified that based on the</p> <p>24 slides plaintiffs' counsel provided -- strike that.</p> <p>25 You earlier testified that based on the</p>	<p style="text-align: right;">Page 277</p> <p>1 are available when we sign out the cases, number one.</p> <p>2 Number two is the attendings, if they have</p> <p>3 questions to ask about the gross specimens, then the</p> <p>4 residents should answer. If they are not able to answer,</p> <p>5 then we have opportunity to pull out the gross specimen</p> <p>6 and then we examine it.</p> <p>7 Q. And the gross specimens that are handled at</p> <p>8 your facility and put into slides, do they look like</p> <p>9 those gross specimens that the plaintiffs' counsel marked</p> <p>10 that purport to show what Dr. Iakovlev had done some year</p> <p>11 and a half later?</p> <p>12 A. Typically the gross specimen in formalin in</p> <p>13 the normal situation is like being processed less than a</p> <p>14 few days, or two to three days, in normal conditions. In</p> <p>15 majority of condition, even just one day, because today</p> <p>16 have surgery, and then next day will be grossed.</p> <p>17 Q. Now, I want to ask you to turn to Exhibit...</p> <p>18 What happens when mesh is left in formalin</p> <p>19 for a long time like was done here?</p> <p>20 A. I think we briefly discussed in the previous</p> <p>21 hours. If the specimen, including mesh specimen, is left</p> <p>22 in formalin for longer time, then the formalin can cause</p> <p>23 change of the shape of the specimen, basically. Okay?</p> <p>24 For instance, because the water element has been lost or</p> <p>25 been removed, then the tissue start to contract.</p>

<p style="text-align: right;">Page 278</p> <p>1 And then also formalin is known to cause</p> <p>2 protein cross linking to each other. This cross linkage</p> <p>3 also can make tissue feel harder, number one, and also</p> <p>4 make the tissue contract if it's elongated shape. If</p> <p>5 it's a round, oval shape, then make them just firmer or</p> <p>6 shrink the tissue.</p> <p>7 Q. Turn to Exhibit 18, the Costello paper that</p> <p>8 plaintiffs' counsel marked.</p> <p>9 A. Yes.</p> <p>10 Q. This is a hernia mesh paper, correct?</p> <p>11 A. Correct.</p> <p>12 Q. And Mrs. Edwards received a 1.1-centimeter</p> <p>13 strip of mesh for her stress urinary incontinence,</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. Plaintiffs' counsel pointed you down to the</p> <p>17 paragraph on the right, first page, talking about</p> <p>18 potential sources of chronic pain, and she mentioned one</p> <p>19 being an intense inflammatory reaction. Do you recall</p> <p>20 that?</p> <p>21 A. Yes.</p> <p>22 Q. Did Mrs. Edwards have an intense inflammatory</p> <p>23 reaction?</p> <p>24 A. For Mrs. Edwards' specimen, we only see mild</p> <p>25 degree of chronic inflammation.</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. And remember we just looked at that hypothesis</p> <p>2 about oxidation referenced in Costello?</p> <p>3 A. Yes.</p> <p>4 Q. Turn, if you would, to page 267, Doctor.</p> <p>5 A. Yes. Hold on.</p> <p>6 Q. Go back one more to page 267. There on the</p> <p>7 top right corner.</p> <p>8 A. No. This is 265. Then suddenly become 270.</p> <p>9 Oh, 267, that's in the next page.</p> <p>10 Q. That's the right page. In the left corner it</p> <p>11 talks about direct oxidation of the polypropylene. Do</p> <p>12 you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And the last sentence in that section states,</p> <p>15 The FTIR analysis neither confirmed nor excluded</p> <p>16 oxidation of PP in the in vivo environment, correct?</p> <p>17 A. Yes.</p> <p>18 Q. So even in this paper it certainly did not</p> <p>19 confirm oxidation, correct?</p> <p>20 MR. FABRY: Objection to form. Leading.</p> <p>21 A. Yes.</p> <p>22 MR. SNELL: I'll rephrase.</p> <p>23 (By Mr. Snell)</p> <p>24 Q. Did the FTIR analysis confirm oxidation in</p> <p>25 this paper?</p>
<p style="text-align: right;">Page 279</p> <p>1 Q. She also, plaintiffs' counsel, pointed you to</p> <p>2 the next sentence that talked about nerve damage from</p> <p>3 entrapment. Did you see that in Mrs. Edwards' case?</p> <p>4 A. I did not see that evidence.</p> <p>5 Q. And is it your opinion that there's no</p> <p>6 histologic evidence of that in Mrs. Edwards' case?</p> <p>7 A. Correct.</p> <p>8 Q. Turning to Exhibit 18, the Clave paper -- hold</p> <p>9 on before you go there.</p> <p>10 Do you remember plaintiffs' counsel read</p> <p>11 to you the last sentence of the abstract about the</p> <p>12 results supporting a hypothesis that oxidation is</p> <p>13 involved with degradation? Do you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. For the polypropylene hernia mesh materials,</p> <p>16 do you recall plaintiffs' counsel reading that?</p> <p>17 A. I recall that.</p> <p>18 Q. Now turn to Exhibit 18, the Clave paper.</p> <p>19 A. This is 18.</p> <p>20 Q. What's Clave? It's probably 19. C-L-A-V-E.</p> <p>21 What's that marked, Doctor?</p> <p>22 A. Yes, 19.</p> <p>23 Q. So, Doctor, your Exhibit 19 is the paper by</p> <p>24 Clave, correct?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 281</p> <p>1 A. No.</p> <p>2 Q. Turn back actually one page.</p> <p>3 A. 265?</p> <p>4 Q. 266.</p> <p>5 A. 266.</p> <p>6 Q. It has the bar chart at the top.</p> <p>7 A. No. I have multiple pages for 270. No.</p> <p>8 Let's see. 266, 267 -- this one?</p> <p>9 Q. That's it.</p> <p>10 A. Yes. Okay.</p> <p>11 Q. Look at the very last paragraph on that page.</p> <p>12 It states, Several hypotheses concerning the degradation</p> <p>13 of polypropylene are described below. None of these,</p> <p>14 particularly direct oxidation, could be confirmed in this</p> <p>15 study. Did I read that correctly?</p> <p>16 A. Correct.</p> <p>17 Q. Turn to page -- I'm sorry -- Exhibit</p> <p>18 Number 20, the paper by Mary, M-A-R-Y.</p> <p>19 A. Yes, I have that.</p> <p>20 Q. You see this was a canine study; it's not a</p> <p>21 study of women with stress urinary incontinence?</p> <p>22 A. Yes.</p> <p>23 Q. Plaintiffs' counsel read a sentence about</p> <p>24 PVDF. Have you seen PVDF studied in any clinical studies</p> <p>25 to treat stress urinary incontinence?</p>

<p style="text-align: right;">Page 282</p> <p>1 A. No. I never see PVDF studies for SUI.</p> <p>2 Q. You have a stack of about 15 different</p> <p>3 professional organization and association statements</p> <p>4 speaking to stress urinary incontinence meshes. Have you</p> <p>5 seen any of those professional organizations, like AUGS,</p> <p>6 SUFU, AUA, who endorse PVDF as a mesh material to be used</p> <p>7 for the treatment of stress urinary incontinence in</p> <p>8 women?</p> <p>9 MS. THOMPSON: Object.</p> <p>10 A. No, I did not see those position statements</p> <p>11 for PVDF.</p> <p>12 (By Mr. Snell)</p> <p>13 Q. Plaintiffs' counsel asked you questions about</p> <p>14 the alleged, quote, bark, close quote, that Dr. Iakovlev</p> <p>15 has testified he thinks is degraded polypropylene, and</p> <p>16 you've testified about your opinions regarding that,</p> <p>17 correct?</p> <p>18 A. Yes, I did.</p> <p>19 Q. Do you have -- and I believe we've marked only</p> <p>20 one or two of your slides regarding your polarization of</p> <p>21 Mrs. Edwards' mesh. But do you have many more slides?</p> <p>22 A. I think so. I have PPT presentation I think</p> <p>23 included. But I just did not include all these pictures</p> <p>24 into my report. So these multiple pictures or multiple</p> <p>25 area showing evidence of those so-called bark-like area</p>	<p style="text-align: right;">Page 284</p> <p>1 compare, you know, what the mesh material should look</p> <p>2 like under those conditions, and then the collagen</p> <p>3 bundles should look like in those two conditions.</p> <p>4 Therefore, the picture basically speaks itself.</p> <p>5 Q. And those are marked just collectively as part</p> <p>6 of Exhibit Number 2?</p> <p>7 A. Yeah. Okay.</p> <p>8 Q. And your nerve filament pictures are also in</p> <p>9 Exhibit Number 2?</p> <p>10 A. I think so. It's there.</p> <p>11 Q. That's fine.</p> <p>12 A. The neurofilament picture is already in my</p> <p>13 report. I mentioned that. That's in Figure 7 in my</p> <p>14 report.</p> <p>15 MR. SNELL: Let's go off the record,</p> <p>16 please.</p> <p>17 THE VIDEOGRAPHER: Off the record 7:58.</p> <p>18 (Off the record.)</p> <p>19 (This portion not on videotape.)</p> <p>20 MR. SNELL: Counsel, we have agreed that</p> <p>21 Exhibit 2 is going to be all the different photos, the</p> <p>22 PowerPoint presentations that Dr. Zheng brought and</p> <p>23 produced, correct, Counsel?</p> <p>24 MS. THOMPSON: That's correct.</p> <p>25 MR. SNELL: So now we can go back on the</p>
<p style="text-align: right;">Page 283</p> <p>1 actually more likely resemble those adjacent collagen</p> <p>2 bundles within the connective tissue. But if you want to</p> <p>3 show -- for instance, this picture, I never showed that.</p> <p>4 Okay. I don't know if you...</p> <p>5 MR. SNELL: Let's mark the whole</p> <p>6 presentation collectively.</p> <p>7 THE COURT REPORTER: It's marked as part</p> <p>8 of Exhibit 2 already.</p> <p>9 MR. SNELL: Oh, Exhibit 2 is marked?</p> <p>10 Okay.</p> <p>11 THE WITNESS: Right. But this is just a</p> <p>12 little bit messy because too much information. I think</p> <p>13 that may take you a long time to sort them out.</p> <p>14 MS. THOMPSON: It will.</p> <p>15 (By Mr. Snell)</p> <p>16 Q. Well, you put labels on those explaining</p> <p>17 what's there, the different magnifications, the staining</p> <p>18 types?</p> <p>19 A. Correct.</p> <p>20 Q. Where the mesh is?</p> <p>21 A. Right.</p> <p>22 Q. How the mesh can appear in different colors</p> <p>23 depending upon --</p> <p>24 A. Right. And then I typically use one picture</p> <p>25 is polarized, then the other picture is nonpolarized to</p>	<p style="text-align: right;">Page 285</p> <p>1 video.</p> <p>2 THE VIDEOGRAPHER: Hold on.</p> <p>3 On the record 8:04.</p> <p>4 (By Mr. Snell)</p> <p>5 Q. Dr. Zheng, we were just discussing part of</p> <p>6 Exhibit 2, the PowerPoint photographs regarding</p> <p>7 comparisons of the HE pictures to those after</p> <p>8 polarization, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And do you also have pictures regarding</p> <p>11 vascular pictures for Mrs. Edwards?</p> <p>12 A. Yes. I have vascular -- normal vascular</p> <p>13 picture looking and also normal nerve looking pictures</p> <p>14 under regular microscope.</p> <p>15 Q. And there's neurofilament staining?</p> <p>16 A. There's neurofilament staining as well as</p> <p>17 normal control from the staining process.</p> <p>18 Q. And the nerve filament staining is specific to</p> <p>19 Mrs. Edwards, correct, besides the control?</p> <p>20 A. Neurofilaments is considered specific antibody</p> <p>21 which recognize nerve fibers.</p> <p>22 Q. And there's photographs of sections that are</p> <p>23 fragmented in the recent recuts from blocks A and B?</p> <p>24 A. Yes. I also took some pictures just in case,</p> <p>25 you know, why I later on do not do further sectionings,</p>

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1 because tissue fragmentation started. Here it is. And
 2 these. So, therefore, a few pictures included.
 3 Q. Okay.
 4 A. But the slides are also still being kept in my
 5 office.
 6 Q. You were asked questions, Dr. Zheng, about
 7 heavyweight versus lightweight mesh, and you testified
 8 from your practice point of view weight is not related to
 9 your opinions. What did you mean by that?
 10 A. Basically I'm a pathologist. I examine tissue
 11 sections. Then based on the tissue section findings, I
 12 generate an opinion. And then, you know, those opinions
 13 usually not related to what kind of mesh or foreign body
 14 materials in it.
 15 Therefore, in terms of light- versus
 16 heavyweight for the mesh material, frankly speaking, I
 17 don't pay attention to that.
 18 Q. All opinions in your report are held to a
 19 reasonable degree of medical certainty?
 20 A. Yes.
 21 MR. SNELL: That's all I have.
 22 MS. THOMPSON: I have just a couple of
 23 follow-up questions.
 24
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1 RE-EXAMINATION
 2 BY MS. THOMPSON:
 3 Q. Dr. Zheng, are you aware of any surgical
 4 procedure that uses Prolene mesh in the vagina?
 5 A. I think in addition to urinary stress
 6 incontinence, there is prolapse also use mesh fiber.
 7 Q. So it's your opinion -- no. I'm not talking
 8 about mesh. I'm talking about suture.
 9 Are you aware of any surgical procedure
 10 that uses Prolene suture in the vagina?
 11 A. I'm not sure, you know, what kind of other
 12 surgical procedures will use this.
 13 Q. Are you aware of any surgical procedure that
 14 uses any permanent suture in the vagina?
 15 A. I think before the Prolene mesh available in
 16 the market, then people use various kind of suture
 17 material, that's true, including like some kind of
 18 biomaterial from animals even.
 19 Q. Yeah. No. I'm asking are you aware of any
 20 surgical procedure that uses permanent suture in the
 21 vagina?
 22 A. I'm not aware of that.
 23 Q. And if Dr. Iakovlev's bark degradation of
 24 polypropylene is published in the peer-reviewed
 25 literature, would your opinion change?

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1 MR. SNELL: Form.
 2 A. Depending on -- I have to see, you know, what
 3 kind of material presented. Then I will generate
 4 picture. I don't usually give an assumption or basically
 5 saying all the published material then represent true
 6 scientific findings. Even we are all aware of many
 7 publications that have defects or limitations there.
 8 (Marked for Identification:
 9 Deposition Exhibit No. 37)
 10 MS. THOMPSON: That's all I have.
 11 And the only additional item is I've just
 12 marked an invoice for Dr. Zheng's expert work on the
 13 Carolyn Lewis case as Exhibit 37.
 14 And I have no further questions.
 15 MR. SNELL: I don't have any.
 16 THE VIDEOGRAPHER: Off the record 8:11.
 17 This concludes today's deposition.
 18 (Deposition concluded at 8:11 p.m.)
 19
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1 SIGNATURE PAGE
 2 I, WENXIN ZHENG, M.D., a deponent exercising my
 3 right to read and sign my deposition taken on April 3rd,
 4 2014, place my signature hereon and make the following
 5 changes on this ____ day of _____, 2014.
 6
 7 _____
 8 WENXIN ZHENG, M.D.
 9 PAGE LINE READS CHANGE TO REASON
 10 _____
 11 _____
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Wenxin Zheng, M.D.

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1 STATE OF ARIZONA)

2 COUNTY OF PIMA)

3 BE IT KNOWN the foregoing deposition was taken
 4 by me pursuant to stipulation of counsel; that I was then
 5 and there a Certified Court Reporter of the State of
 6 Arizona, and by virtue thereof authorized to administer
 7 an oath; that the witness before testifying was duly
 8 sworn by me to testify to the whole truth; pursuant to
 9 request, notification was provided that the deposition is
 10 available for review and signature; that the questions
 11 propounded by counsel and the answers of the witness
 12 thereto were taken down by me in shorthand and thereafter
 13 transcribed into typewriting under my direction; that the
 14 foregoing pages are a full, true, and accurate transcript
 15 of all proceedings and testimony had and adduced upon the
 16 taking of said deposition, all to the best of my skill
 17 and ability.

18 I FURTHER CERTIFY that I am in no way related
 19 to nor employed by any parties hereto nor am I in any way
 20 interested in the outcome thereof.

21 DATED at Tucson, Arizona, this 14th day of
 22 April, 2014.

23

24 _____
 Bonnie J. Humm

25 Certified Court Reporter #50722